EXHIBIT 1

Deposition of:

Becky Smith

April 24, 2017

In the Matter of:

Smith, Becky vs. C. R. Bard, Inc.

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C.R. BARD, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION — MDL NO. 2187

THIS DOCUMENT RELATES TO:

BECKY SMITH,
Plaintiff,

v. — No. 2:15-cv-16402

C.R. BARD, INC.,
Defendant.

DEPOSITION OF BECKY SMITH
Taken on behalf of Defendant

BE IT REMEMBERED THAT, pursuant to notice, the deposition of BECKY SMITH was taken before Heather L. Fairless, a Registered Professional Reporter and Certified Shorthand Reporter, on Monday, April 24, 2017, commencing at the hour of 9:50 a.m., in the offices of LNS COURT REPORTING & VIDEOCONFERENCING, 1123 S.W. Yamhill Street, Portland, OR 97205.

APPEARANCES:

WAGSTAFF & CARTMELL LLP
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Attorney for Defendant

Also present: Don Mackie

* * *

BECKY SMITH,

Having first been sworn by the Certified Shorthand Reporter to tell the truth, testified under oath as follows:

MS. COLLINS: This will be the deposition of Becky Smith. This deposition is taken for purposes of discovery and all other purposes allowed under the Federal Rules of Civil Procedure, the MDL 2187 deposition guidelines and Pretrial Order No. 40 as amended by Pretrial Order No. 236.

Jeff, can we agree that all objections except as to form and motions to strike are reserved?

MR. KUNTZ: Yes.

EXAMINATION

BY MS. COLLINS:

Q My name is Leah Collins and I represent Defendant C.R. Bard in this matter and we just briefly met for the first time before this deposition. Correct?

A Yes, that is correct.

Q And have you ever had your deposition taken before?

A No.

Q Okay. So I am just going to go over a few ground rules with you. So as you see, we have a court reporter here that will be transcribing everything today. So please try to answer verbally because she can't record like a head nod or a shoulder shrug or anything like that. And do you understand that you are testifying under oath as if you were testifying in court?

A Yes.

Q If you don't understand a question, please just let me know and I will rephrase it. If your counsel objects, you can go ahead and still answer the question unless he advises you otherwise; do you understand that?

A Yes, I do.

Q Try not to answer before I am done asking the question so that way we aren't interrupting each other and we can keep a clean record for the court reporter. And then if you need a break at any time, just let me know. The only thing I ask is that if I have asked you a question, that you answer it before we go and take a break.

A Okay.

Q Are you currently taking any drugs or medications that would affect your ability to

testify, comprehend, or remember details or affect your memory in any capacity?

A I am not.

Q Are you on any prescription medications right now?

A Yes, I am.

Q What prescriptions are you taking?

A I take Singulair, which is for allergies.

Q And do you know the dosage of that?

A 10 milligrams, I believe.

Q Okay.

A And I also take a depression medicine which is Lexapro and it is also at 10 milligrams.

Q And is there any other reason that your memory or details would be affected in any capacity today?

A No.

Q And do you agree to give your full and complete testimony here today?

A Yes, I do.

Q Would you please state your full name for the record?

A Becky Rae Smith.

Q And have you ever been known by any other names or aliases?

A I was Becky Reding and Becky Ockenfels.

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Q Could you spell Ockenfels please.
A It is O-C-K-E-N-F-E-L-S. Reding is with one D.
Q And what is your date and place of birth?
A I was born in Seaside, Oregon, and I was born on January 30, 1959.
Q And where do you currently live?
A Nehalem, Oregon, [redacted]
Q And does anyone live with you?
A My husband Don.
Q Anybody else?
A No. I have a dog and a cat. They wouldn't like it if I ignored them.
MS. COLLINS: I would like to mark as Exhibit 1 the notice of deposition of Becky Smith.
(Exhibit No. 1 marked.)
Q BY MS. COLLINS: If you could just take a look at that document and review it. Have you ever seen this document before?
A Yes.
Q And did you bring any of the documents with you in response to Exhibit A?
MR. KUNTZ: I am just going to, one, incorporate our objections to the notice here and, two, that a lot of those documents were produced

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pursuant to the plaintiff's fact sheet.
But go ahead and you can answer.
THE WITNESS: I have nothing with me.
Q BY MS. COLLINS: Okay. You are aware that you are asserting a personal injury claim against Bard. Correct?
A Yes.
Q Okay. And you are alleging that the constant heaviness and ache in your pelvic area, the severe pain during intercourse, the fear of exercise except for walking, and your weight gain are all caused by the mesh implant. Correct?
A Correct.
Q Are there any other issues that you relate to the mesh implant that weren't listed on your PFS?
A Well, after thinking about it, my husband and I have had counseling a couple of different times. And thinking back, I absolutely believe that has something to do with our -- the mesh implant. Just the whole sexual issues have been very difficult for me and I have actually kind of kept it to myself that there was pain during intercourse. I mean, my poor husband just found out recently that that is the case. And so our relationship had been strained to say the least. So two different times we went

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through counseling.
And right now I am seeing a doctor, regular practitioner and I have started on an estrogen regime right now, trying to address the aching in my pelvis. And so that is the first part and it has been a month and that has not changed. And so I assume we are going to see -- her and I had talked about seeing someone else about what else needs to be done, what else can be done. So I am not sure where that is going. So that is starting and kind of ongoing.
Q And who was that doctor that prescribed you the estrogen regimen?
A Her name is Shawn and I don't know how to spell her last name. It is like Kuehl, K-E-U-E-L (sic). There is an H in there. I think I gave it to Jeff at one point.
MR. KUNTZ: I think it is in the fact sheet, I think.
THE WITNESS: It had been added right at the very end because I called and said, hey, I am just seeing a new doctor.
MR. KUNTZ: Can we go off the record?
(Discussion off the record.)
Q BY MS. COLLINS: So just to be clear, the

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other issues are the counseling and the estrogen regimen from Dr. Shawn Kuehl. Correct?
A I am not even sure if it is the estrogen regimen but it is the looking into -- looking into my issues with maybe the bladder, the mesh. So I assume that is what it is. I am not -- I can't say it because we just started.
Q When did you start that?
A About five weeks ago.
Q And what is the treatment that she has you doing?
A I just have estrogen that I use at night. It is inserting of estrogen.
Q Okay.
A I am going to be doing that for six weeks and then contact her if it is not -- if it hasn't changed.
Q And what was the purpose of this -- of inserting of the estrogen?
A To try and alleviate the pain that I have, the dull aching pain from -- to see if that would help. And I believe that would affect the tissue in some way.
MS. COLLINS: All right. I would like to enter as Exhibit 2 Becky Smith's Plaintiff

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Fact Sheet.
(Exhibit No. 2 marked.)
MR. KUNTZ: Where is my copy?
MS. COLLINS: Would you like a copy, Jeff?
MR. KUNTZ: No, I am good.
Q BY MS. COLLINS: So if you could just take a second to review that.
A Oh, my God. This took so long to fill out. Yes. It all looks so familiar.
Q So is that your signature on the last page verifying that all responses are true and accurate to this document?
A Yes, it is.
Q Okay. And as you sit here today, are all these responses still accurate?
A Yes, except what I just mentioned.
Q Right, except for the ones that you wanted to add?
A Uh-huh.
Q And did you personally complete this form?
A Yes.
Q Did your attorneys help you fill it out at all?
A No.

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Q If you could turn to page 6, question 6A, it says, "Describe the bodily injuries including any emotional or physical injuries that you claim resulted from the implantation of the pelvic mesh products." And in support of that you wrote, "I have constant heaviness and frequent ache in my pelvic area when I walk or am active for any length of time, severe pain during intercourse which has completely changed our intercourse options and has caused me to feel guilty about getting the mesh implant, fear of exercise except for walking due to the mesh coming loose again and causing me more pain, and I have gained 15 pounds because of this." And you are claiming that those issues were all caused by the mesh product. Correct?
A Yes.
Q And on page 7, question 6E it asks whether you are currently experiencing symptoms related to your claimed body injuries, and you checked yes and wrote, "I have a dull ache in my pelvic region any time I am not laying down, painful intercourse severe enough to curtail having intercourse except on rare occasions." And you are not currently -- and so you are claiming that all of those are a result of the mesh implant. Correct?

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A Yes.
Q Okay. So I am just going to walk through some of these claimed issues just to get a little bit more detail about them. So can you tell me a bit about the constant heaviness and frequent ache that you have in your pelvic area?
A It is something I have never felt before and it is -- when I sit, there is a heaviness and just sort of an emanating ache. It is like this really dull ache. There is no sharp pains except if I move wrong or, you know, like get up or sometimes there is, but generally it is just this dull ache. And the more tired I get, the more it hurt -- you know, the more that seems to -- I don't know if I just notice it more. But walking, we take a walk a couple miles, you know, two or three times a week and it is always noticeable during that period of time. So it is just a strange dull ache that is exhausting actually.
Q And where do you feel the ache generally?
A It is in my pelvis back towards -- not at the anal area but back inside.
Q Okay.
A So when my doctor did an exam this last time, she asked me, is this where it hurts? And I said,

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yeah. And she said, well, that is where the -- she said, well, it looks like it might be where the bladder sling and the mesh are, right where they are. So she actually did an examination.
Q And when was the time -- when did you see her for that examination?
A The same -- that was that Shawn Kuehl so five weeks ago.
Q Five weeks ago?
A Uh-huh, about.
Q Okay. And would you say the ache that you have in your pelvic area is worse towards the end of the day than it is at the beginning of the day?
A No. Doesn't change except if I am busy. You know, but really it is there all the time. When I wake up in the morning, it is there.
Q And did you ever have that type of pain before the mesh implant?
A That is the only -- really, that is the only reason I say that it has to be because of the implant, because I did not have anything like that.
Q And are there any activities -- I know you briefly described your walking with your husband. Are there any activities where you feel that pain more so than at other times?

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A Well, exercising has been a big issue. Yoga. You know, I used to do Zumba and all kinds of things and I just really had to stop doing it because of the pain.
Q So you did those activities prior to the mesh implant. Correct?
A I did them prior to and tried afterwards.
Q Okay. And what was your experience with doing yoga and Zumba and exercising after the mesh implant?
A I had to stop doing it because of the pain. I wasn't able to sustain it even for a whole session.
Q And was that pain the same that you described as the heaviness and the dull pain or was it a different type of pain that you experienced?
A It was the same dull pain but then there was also those sharper pains.
Q And when would you feel those sharper pains?
A Just as I was doing the activity itself, you know, movements with your body --
Q Okay.
A -- kicking legs and that kind of thing, and yoga, you know, with the stretching, any time you are using your hips and moving them from side to side.

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Q And is there anything that helps relieve that ache and that pain that you feel?
A I don't do much to alleviate it except take Tylenol or Aleve or ibuprofen.
Q And do those help at all?
A I think they make me feel better. I am not sure if it helps because I feel like I am doing something maybe. It gets pretty frustrating.
Q And does that type of pain -- I know that you said you feel it first thing in the morning. So is that a constant pain or is it intermittent and kind of related to certain activities?
A It is constant. I mean, I feel it right now. I have done, you know, nothing.
Q On a scale of one to ten, how would you rate that pain that you feel?
A Since it is constantly in my mind, I would say it is at least a four.
Q And have you seen a physician or talked to a physician about that pain, the pelvic pain that you feel?
A Uh-huh.
Q And who have you -- who did you go see?
A Let's see. So the pain from the first mesh implant, I saw the same doctor a year later when the

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pain -- when I was bleeding, so I had the mesh removed, part of it.
Q Sorry. Which doctor was that? You mean the same as your implanting physician?
A Uh-huh, Dr. Kim.
Q Okay.
A So that was the first doctor I saw about it.
Q Okay. And she removed the mesh implant. Correct?
A Part of it, not all of it. It is still there. Just part of it.
Q And what did she say about the pelvic pain you were experiencing?
A That the mesh had come loose. The tissue was eroding, that when I had the surgery, she didn't really know what the surgery was going to be like. And then after I had the surgery, she said that she was able to just trim it up so she said she hoped that would help with the pain. She assumed it would help with the pain.
Q And did she give you any other options besides trimming -- going in to trim the mesh implant to help relieve the pain?
A Not that I recall.
Q And did she ever tell you that the pain you

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were experiencing was related to the mesh implant?
A Directly related. I mean, it was obvious. The bleeding was there. You know, I mean, it is poking out. It is mesh. It is like -- so I don't think it was hard to figure out.
Q And what about Dr. Shawn Kuehl? Did you ever see her about the pelvic pain you were experiencing?
A Just recently.
Q And what did she have to say about that?
A She actually consulted another doctor in the office. She just said, well, let me just find out about this, because, you know, she looked in there. I told her that is where the pain was. She said, well, you know, I see this -- you know, this mesh and you have got this sling and they are pretty immovable. So she said, I am going to go ask. So she asked the OB-GYN. So she said -- after they talked, she said, well, we are going to do an estrogen cream and then if that is still not going to work, then we need to see her about it.
Q Do you know the name of the OB-GYN she consulted with?
A I do if I can think of it. It is -- can I come back to that --
Q Yeah.

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A -- if I think about it? Okay. I will try and remember. Dr. Gerken. But I don't know how to spell it. G-E-R-K-I-N (sic). And she is from Tillamook.
Q Okay. So let's move on to talk about the severe pain that you experienced during intercourse. So when did that pain start for you?
A I can't -- I mean, I don't remember the very first time. Since it was surgery, I think that I just assumed that things were mending and that maybe they would change over time, get easier, and it just hasn't been the case so there has been pain for years, I would say, since the implant.
Q And how long after you had the mesh implant -- what was the gap between that date and when you first had intercourse again?
A It had to be at least two months and that is the first time. It had to be at least two months.
Q And did you feel pain at that point?
A Uh-huh.
Q Is that a yes?
A Yes. I am sorry. I forgot. Thank you, yes.
Q So the PFS indicates and what you stated in 6A is that you had to change your intercourse options. So what did you mean by that?

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A Well, you know, face-to-face, you know, back to front, those kinds of positions have changed just because trying to make things more comfortable and that just has not worked as well so...
Q So are there any positions that you feel the pain more so than other positions?
A Uh-huh, absolutely.
Q And when you do change positions, are you able to have intercourse without feeling that pain?
A No. It is just lessened. I mean, it is debilitating, really.
Q Your PFS also indicates that you feel guilty about getting the mesh implant. Could you kind of talk to me about that a little bit?
A Well, my husband and I have had a hard time -- I personally have had a hard time telling him that we have had pain during intercourse because I know that he is such a sweetheart, such a gentleman that he would not want that part of his life at all, you know. And so obviously being a married couple you want to have sexual activity. And so for me it was -- you know, I tried to hide it. I avoided sex and I wasn't even at first sure really why I was doing that and then just realizing how painful it was. What was your question again? I am sorry.

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Q No, you answered it. I just wanted to know -- you wrote in 6A here that you felt guilty about getting the mesh implant so I just kind of wanted to talk to you about that.
A So it has changed our life completely. I mean, honestly I had no idea that having that mesh would have anything to do with our sexual activity, that it would change it at all. And I obviously did not want that to happen.
Q Where exactly do you feel the pain during intercourse? Is there a specific region that you feel it more so than --
A Uh-huh, towards the back of my vagina.
Q And is that the same area or a different area than where you experienced the dull aching pain?
A It is the same area.
Q And can you describe the type of pain that you feel?
A That is sharp pain.
Q Okay. So in that regards it would be different than the pain that you feel --
A It is in the same area but it is more intense.
Q Okay. And how long does the pain last?
A Really just during intercourse, that kind of pain, and then it goes back to the dull ache.

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Q And is there anything that makes that pain that you feel during intercourse worse?
A I don't know how to answer that. I don't know.
Q Okay. What about certain positions? Does that make the pain worse at times than others?
A Yes. It can absolutely be worse because of the position or the thrusting or, you know, whatever the strength of the thrust, I guess.
Q Is this type of sharp intense pain -- is that somewhat similar to the pain that you experience when you exercise or do yoga that you were describing earlier?
A Is it similar, yes, but the intercourse is more intense.
Q Okay. And does that pain end after or once intercourse stops?
A The sharp pain, yes.
Q And have you seen a physician about the pain that you were experiencing during intercourse? Is that a no?
A I am trying to think.
Q Okay.
A I talked to Dr. Kim during the second surgery about it and she just thought that the trimming the

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mesh would alleviate that.
Q And did it alleviate that pain?
A No.
Q Did you see any other doctor and talk to any other doctor about the pain during intercourse you were experiencing?
A You know, I am not sure that I have -- I have never been treated for it so I am not really sure that I talked to anybody about it. It is pretty embarrassing so I didn't even talk to my husband about it so...
Q Okay. So you also state in the PFS on question 6A that you have a fear of exercise except for walking due to the mesh coming loose again. Can you tell me what you mean by fear of exercise?
A Well, I mean, I don't want to take on a yoga class. I don't want to go with my friends to Zumba class because it is pretty embarrassing when I have to stop in the middle or, you know, double over with, oh, my gosh because -- and the pain is severe and then I just end up not continuing with it and so, yeah. So fear of exercise is basically I don't want to take it on because it really does hurt.
Q Okay. And what type of exercises did you engage in before the mesh implant?

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A Like I said, I have done yoga. I have done Zumba. I have done aerobics. I just went to the weight room, elliptical machines, just the whole gamut at the fitness center.
Q And how often would you exercise prior to the mesh implant?
A Just go in, you know, kind of spurts, do it three or four months at a time and then not and then start it up again.
Q And can you exercise at all now?
A I walk. I feel like that is exercise.
Q Are you able to lift any weights at all anymore?
A I don't lift weights.
Q So it also says that the mesh came loose. Can you talk to me about what happened when that -- or how the mesh came loose?
A Well, I don't know how it came loose but when I noticed it, I was exercising with my son and daughter-in-law and we had started this routine and we met every week, I don't know, two or three times a week and we would do a video and we would exercise, and we had probably been at about four weeks of that and, you know, there was pain and all of that but then I just started just bleeding and so

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I quit and I, you know, went home and I told Don, you know, that I had this -- you know, I was bleeding. I was really afraid because it had only been a year since -- not even a year since I had had the implant put in. And Don said, well, you know, Becky, there is -- you know, when we made love the last night, there was this really sharp scraping in there. So anyway I think we investigated and there really was just mesh poking out. And so the mesh had -- so that is where the bleeding was from. It was from my vaginal cavity.
Q And what do you mean by a sharp scraping that Don described?
A You will have to ask him about it but I assume when we were making love his penis was scraping against the mesh.
Q Okay. And what type of pain did you experience when -- with the bleeding and the mesh coming loose?
A Really dull aching was seriously, you know, more intense and it was the sharp pain from -- I assumed from the cutting of the tissue.
Q And did you see a doctor when the mesh came loose?
A I went -- that is when I made appointment to

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see Dr. Kim again because she is the one who had done it. So I think I saw her in December or the first part of January and then I had the revision surgery in -- at the end of January.
Q Okay. And do you know how long after the mesh implant procedure was done that it came loose?
A I just know that the two surgeries were a year apart.
Q Okay.
A So, you know, I don't know how long it had been loose. I don't know that. I am sorry.
Q Okay. And did Dr. Kim tell you or give you a reason of why the mesh implant would have came loose?
A You know, I don't recall.
Q Okay. Did she talk to you -- did she have any conversation with you at all about how it came loose?
A You know, I would just be guessing to say -- I honestly just do not remember. I assume she just said this happens sometimes, you know, because the tissue is growing around it and maybe it didn't grow around it. I mean, in my head that is what I think she said so I am guessing though.
Q Okay. And you also state at 6A of the PFS

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that you have gained 15 pounds because of the mesh implant. So can you tell me a bit more about your weight gain?
A I think it is just because of the exercise that I haven't been able to do and it has been a struggle. I am just going to say I know 15 pounds doesn't seem like a ton to some people but I have never been terribly overweight and it is pretty disturbing. But anyway, it is really -- I am not going to say it is from the mesh. It is from the inability to exercise rigorously. Walking is for old people. Sorry, but it is. I mean, my parents walk.
Q Did you ever try changing your eating habits after the mesh implant to help with the weight gain at all?
A We diet regularly. It is not -- yeah, we just diet healthfully.
Q What type of healthful diets do you usually engage in?
A No sugar, you know, lots of vegetables and fruit, yogurt, you know, no snacking, just reduction of high-calorie foods.
Q And do you have any family history of obesity or weight gain at all?

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A Not myself, no.
Q Do you have any family history of thyroid conditions?
A No.
Q Have you been diagnosed with a thyroid condition?
A No.
Q Did you see a physician about the weight gain issue at all?
A It is always a conversation that I bring up. They don't generally bring it up but I bring it up.
Q Who did you talk to about that?
A Every doctor I have ever had just, you know, with the yearly physicals and things like that.
Q And what did they tell you?
A Reduce your food, walk, just the things that I do.
Q And has any physician that you saw ever told you that the Bard product was a -- or was related to your weight gain?
A They didn't even know I had the Bard, I don't think.
Q Okay. Has any physician ever told you directly that the Bard product caused injury to you?
MR. KUNTZ: Objection.

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Q BY MS. COLLINS: You can answer.
A Dr. Kim made it very clear that the mesh poking through definitely was the cause of the bleeding and the pain. There is no other reason for it.
Q And this was before she went in and did the second procedure of the trimming. Correct?
A I assume so.
Q Has any physician ever told you that the issues that you claim you are experiencing is Bard's fault?
A No.
Q Has any physician ever been critical of Bard or its products in your presence?
A No, not at all.
Q So who are your current physicians?
A Just Shawn Kuehl. In the last two years my physicians have moved. I have had two different ones and so this is a very new one.
Q And is she your primary care physician?
A Yes.
Q And do you have a current gynecologist?
A I do not.
Q Do you have a current psychiatrist or psychologist?

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A I do not.
Q Do you have a pain management doctor?
A No.
Q And when was the last time you saw a physician?
A Five weeks ago.
Q And I know you said before that Dr. Kuehl spoke with an OB-GYN. Did you ever see that OB-GYN?
A In the hall I did.
Q But you never had an appointment with her?
A Uh-uh.
THE REPORTER: I am sorry. In the hall I did?
THE WITNESS: Yeah, when I was going in and out of the room. I know her. I mean, we are in a local area so...
Q BY MS. COLLINS: But she never came in to the exam room to you?
A No. Shawn went out and talked to her.
Q You said at the beginning of this deposition that you and your husband had gone to counseling?
A Uh-huh.
Q When did you first start going to counseling?
A I can't really say that first time. It has been a while. We were trying to remember on the way

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here because I had said, well, what about the counseling? So I can say it was at least six or seven years ago but not longer than that. And it was just somebody from the hospital. And then the most recent one -- and we just saw that woman for a couple months, maybe three or four months. And then the most recent one is --
Q Sorry. Do you remember the name of that counselor that you saw at the hospital?
A Nope.
Q Okay. And then the most recent one, go ahead.
A Amy Pulitzer and she -- we saw her for -- every week for about six or seven months. Sometimes we would see her individually. Sometimes we would see her together.
Q And what was the -- and where is Amy Pulitzer located?
A In our area, Manzanita, Oregon.
Q And when was the last time you saw Amy Pulitzer?
A I am just guessing two and a half years ago maybe. I mean, I am not sure, but about that. Time flies though.
Q And what was the purpose of going to see her?
A We were having trouble communicating and so we

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went into couples counseling. We really were -- like I said, trouble communicating was huge.
Q And why did you stop going to see Dr. Pulitzer?
A We felt like we were on a good footing. We were ready to work on our issues on our own.
Q So prior to your implant surgery, what medications were you currently -- what medications were you taking on an ongoing basis?
A The same, Singulair, Lexapro. I think it was Lexapro. I took one other medication that was similar to Lexapro and I switched but I don't know when that was so...
Q And the Lexapro is for --
A Depression.
Q Depression, okay. And who prescribed you the Lexapro?
A I think it was Lynn Hoth. She is a physician in Seaside. I had her for a pretty long time until my insurance changed and didn't cover that insurance anymore -- or that company anymore.
Q And who is now filling that prescription for the Lexapro?
A Shawn.
Q And how long have you been on Lexapro?

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A Over ten years, over 12 years probably.
Q But you were on it before your implant surgery?
A Uh-huh, yes.
Q And do you keep a journal or a diary at all?
A Sometimes, not on a regular basis.
Q And when did you start keeping a journal or a diary?
A When I was in high school. I should say I don't keep a diary or journal on a regular basis. I write things down occasionally like on a calendar or -- but it is not like this is how I am feeling today. I don't do that.
Q And do you tweet or blog at all?
A No.
Q Do you have a Facebook page?
A I do.
Q Is your page on private?
A I have no idea. And I don't post things on it. I read things on it. I like things on there.
Q And are you on any other forms of social media platforms?
A I don't think so.
Q You never know these days.
A Pinterest. I look at Pinterest but I suppose

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that is not one.
MR. KUNTZ: I love Pinterest.
THE WITNESS: Me too.
Q BY MS. COLLINS: Have you ever posted on any social media blog or message board anything concerning the transvaginal mesh or Bard?
A Nope.
Q So I just want to talk a bit about your prior medical history. How many times have you been pregnant?
A Six.
Q And how many vaginal deliveries have you had?
A Six.
Q And did you have any vaginal tearing or lacerations or did you need to be stitched up after delivery?
A My second child. I had a double episiotomy.
Q Was a vacuum ever used during delivery?
A No.
Q Were forceps used during delivery?
A The second child had forceps.
Q Your other four children didn't have forceps?
A The five.
Q Five children?
A No.

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Q Okay. And did you have any pelvic pain after delivery?
A I don't -- well, delivery itself is a little bit painful so I don't think there was additional pain.
Q What about after the delivery, not during the delivery?
A I don't know. I don't think so. My oldest child is 40 years old. That is a long time ago.
Q Did you have any complications after any of the deliveries?
A No, I did not.
Q Have you had any miscarriages before?
A No.
Q Have you had any abortions before?
A No.
Q Aside from the surgery, two implants, and then explant part of the Bard mesh, have you ever had surgery on any other part of your pelvis?
A At the same time I had the mesh, I had a hysterectomy.
Q And was that a total hysterectomy or what type was that?
A I still have my ovaries.
Q In terms of approach, do you know if it was

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done abdominally or vaginally?
A It was done vaginally.
Q Have you ever had fibroids before?
A Yes, I have.
Q When did you have those?
A I had a fibroid -- I think it was like 2002, something like that.
Q And what was the treatment for that?
A All kinds of treatments. I have always had -- the reason that I even knew about it is I have always had -- I have been anemic because of my menstrual cycles have always been very heavy and so I have had anemia. And at that time my anemia was really severe and so I saw a specialist, Dr. Mitchell, and he did not believe in hysterectomies at the time and so he said that we needed to do these procedures beforehand, you know, and so one of them they found that -- he saw that I had a fibroid so I was on medication to reduce the fibroid. Then they were going to go in there and take it out, but when he went in there, the fibroid wasn't there. So I don't know what to tell you about that. Had them, didn't have them. Who knows?
Q Have you had tubal ligation?
A Yes. I had a tubal ligation.

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Q And when was that?
A For my 30th birthday.
MR. KUNTZ: Oh, wow.
THE WITNESS: Happy birthday. Right? So that was in like '89.
Q BY MS. COLLINS: Have you ever had any sexually transmitted diseases or infections?
A I have not.
Q Aside from your pelvic issues, have you had any cardiac or pulmonary issues?
A No.
Q Have you -- do you have any kidney or thyroid issues?
A I do not.
Q Have you ever had cancer?
A No.
Q Have you ever had heart disease or hypertension?
A No.
Q Do you have diabetes?
A I do not.
Q So your PFS also states that -- I mean, we briefly talked about the weight gain issue so I just want to go into it, A, a bit more. Do you happen to know what your body mass index is?

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A No.
Q And have you made any changes to your diet regimen compared to before the implant and how you eat now?
A I definitely -- I don't know. I always eat well so I would say that there is no change.
Q And has the weight gain impacted your activities to work at all?
A No, it has not.
Q Has it impacted your ability to do household chores?
A No.
Q What about your ability to exercise?
A I don't know if it is the weight gain or the pain. I am not sure what is causing it.
Q What about has it impacted your ability to do social activities?
A My ability or my desire?
Q Let's start with your ability.
A No.
Q What about your desire?
A Yeah. It is hard to be overweight, be in public places.
Q Do you have any leg, back, or spine issues?
A I do not.

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Q Have you ever had any pain in your neck or back?
A Uh-huh. I have pulled a muscle now and again.
Q What about pinched nerves?
A Probably but I don't remember, nothing like long lasting or significant.
Q Nothing that you have been diagnosed with. Correct?
A Not that I know of, no.
Q And have you been diagnosed with any form of arthritis?
A No.
Q You seemed hesitant about that.
A Well, because I think I have arthritis in my hands but I don't believe that that has actually been a diagnosis.
Q Okay. What type of pain do you experience in your hands?
A Just thumb sort of pain and I have had a steroid shot in my wrist, so...
Q What was the -- who gave you that steroid shot?
A Some doctor at the local clinic.
Q What was the purpose of it?
A To relieve the pain.

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Q Did he ever tell you what type of pain would have caused -- or what type of pain it was?
A He did. He said that it was -- it is like a pulled muscle or something and it is actually a condition. It is called Quervain's something. I don't remember what it is but it is like tendinitis, similar to that.
Q Have you ever been on any pain therapy for any chronic pain conditions?
A No.
Q Do you smoke cigarettes?
A No.
Q Did you smoke cigarettes?
A Never. Very proud of that.
Q Do you drink alcohol?
A Occasionally.
Q How often would you say?
A On average once every two weeks.
Q And aside from the issues that we have discussed, have you ever had any other significant health issues throughout your life?
A Not that comes to mind.
Q On page 10 of your PFS it indicates that you had a uterine ablation in 2002 from Dr. Mitchell Strauss.

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A That was the fibroid.
Q Okay. And when that surgical procedure was done, he didn't find any fibroids. Correct?
A Right.
Q Did he do anything else during the procedure?
A I have no idea. I don't think so. Like what? I think it was just a scraping of the uterus to make sure that it was -- I think he was trying to slow the bleeding down.
Q Right. That is what I wanted to make sure just because if -- just because he didn't see a fibroid doesn't mean he went in and didn't do anything so I just wanted to see what he had done during that procedure.
A I think he continued with the ablation.
Q Okay. And did that procedure help with the heavy bleeding that you were experiencing?
A No.
Q So do you still -- or did you still experience heavy bleeding after that procedure?
A Yep.
Q And have we discussed all of the pelvic related issues, significant medical procedures, and hospitalizations that you have undergone before the Bard mesh implant?

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A I feel like we have.
Q Is there anything else that we haven't talked about?
A Tubal ligation, the ablation. I think that is it. I feel like I have been really a healthy person. Very lucky to be healthy.
Q And we talked briefly that you had been prescribed antidepressants. Do you recall when you first started them?
A No. I would say, gosh, about the same time as the ablation and all that so I would say around 2002 or '4 or somewhere around there. I don't recall exactly.
Q And why were you placed on antidepressants?
A Well, I had gone through a period of like six weeks of no sleep, just huge, you know, mood issues, a bunch of depressive signs.
Q Do you know why you went through that period of no sleep?
A No, I do not. I just was assuming it was because I was depressed and I think that being depressed is -- you know, it doesn't have anything to do with me. It has to do with my system working.
Q But there was no significant event that --
A No.

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Q -- would have caused --
A No.
Q Who first diagnosed you with depression?
A Lynn Hoth, I think.
Q And you experienced depression before you were implanted with the Bard product. Correct?
A Yes.
Q And you were prescribed antidepressants before you were implanted with the Bard product. Correct?
A Yes.
Q Did you and your husband ever seek mental health counseling or therapy or marriage counseling before the implant surgery?
A Yeah. I think we did.
Q Do you recall when that was?
A The year before we married.
Q And why did you go see a counselor?
A To see if we were habitable, co-habitable together, sort of figure things out, see if it was a good decision. I had already made two bad ones so...
Q And have you personally without your husband ever sought counseling or therapy from a mental health professional?
A No. You mean like a psychologist or -- yes,

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no.
Q Did you ever go to therapy at all on your own?
A I don't think so.
Q So this next line of questions is going to relate to your experiences and your symptoms before the implant surgery and then I will let you know when we are shifting to after.
A Okay.
Q So what pelvic symptoms were you experiencing prior to the implant surgery that caused you to get the surgery?
A I went in for a hysterectomy. The hysterectomy doctor is located in the same place as the urologist which is Kim. So when I went for the hysterectomy, she is a specialist. She was recommended from my nursey (sic) friends around where I live. So I went to see her and she also had asked me about incontinence and other issues and she said, well, you know, I have a colleague upstairs that does that. Do you want to -- you know, we should talk to her. So I said, okay. And so I went up and talked to the urologist and we decided through our conversation that I was a candidate for a sling, a bladder sling and I assumed the mesh at the same time.

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Q And what was it that -- with that conversation that they decided that you were a candidate for the mesh and the bladder sling?
A Well, I had pretty severe incontinence. Severe as in walking too fast, sneezing would cause leakage and so -- and I still had -- I had -- you know, I couldn't completely relieve my bladder. I didn't know that but that was the case. She demonstrated that. And then during the exam, she talked about the sling and then she said that it would be a good idea to do this mesh as well to build up the vaginal walls.
Q And how frequently did you experience incontinence on a daily basis?
A Daily. How often?
Q Yeah.
A Many times.
Q Did you ever have to wear a pad during the day?
A Uh-huh.
Q How many would you go through a day, would you say?
A Oh, one. One or two. Two, I would say.
Q And how frequently would you have to urinate during the day?

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A That is a great question. I am not sure about that. I am sorry.
Q Would you say it was more than normal prior to having children?
A You know, it wasn't the urgency to go. That was not my issue.
Q So what would you say the issue was?
A The leakage, yeah.
Q And did you have any abdominal pain before your implant?
A Uh-uh -- no. Excuse me.
Q Did you have any of that discomfort in your pelvic area before your implant?
A No.
Q Did you ever get bladder infections or UTIs prior to the implant?
A No.
Q Did you have a bulge prior to the implant?
A A bulge?
Q A bladder bulge at all?
A I don't know.
Q Did you ever experience constipation before your implant?
A Not as a medical issue.
Q Did you ever have a sensation that you

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couldn't completely empty your bowels at the end of a bowel movement?
A I don't know that either.
Q Did you ever have pain during sex prior to the implant?
A No.
Q How did the incontinence impact your life?
A I always had to bring extra clothes. You know, I was always aware of how close a bathroom was or, you know, wondering what the activities -- how strenuous they were going to be, make sure I had extra pads.
Q The leakage that you experienced, would that occur more with strenuous activity?
A Uh-huh, yes.
Q Were you still able to work?
A Uh-huh, yes.
Q I was just waiting for you to swallow.
A Thank you.
Q Were you still able to do household chores?
A Yes.
Q Were you restricted at all in what you could do at home?
A No.
Q And would you say that your symptoms were

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getting worse over time?
A Yes. Yes, I would.
Q How so?
A Well, the incontinence was more frequent and more serious. It wasn't just a drop anymore.
Q And would you say that that was a result of -- strike that.
Was it worse after your first childbirth compared to your last childbirth?
A No. Really that did not change -- my incontinence didn't change until just before I went in. It was like the last two or three years before that that caused -- that it was noticeable.
Q Okay. Did you experience incontinence after your first childbirth?
A No.
Q When would you say that the incontinence started?
A I would say it was after, you know, I did all the ablation and that, so I think it was, I don't know, just before I went in for the hysterectomy. I just think things were just really quickly changing. It was a little scary actually. So maybe since I had -- it was '08 so I would say by '06 probably, '07.

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Q What year was your last child born?
A '86.
Q And you didn't experience any incontinence between the period of '86 to about '06 or '07?
A Not as a problem, no.
Q Okay. So as a result of the incontinence you made the decision to seek the help of a physician. Correct?
A Uh-huh.
Q And you ultimately saw Dr. Kim as a solution for your problems. Correct?
A Yes, through my -- through the other doctor. I remembered her name a little bit ago, but she is the one who suggested I see Dr. Kim.
Q So you were referred to Dr. Kim?
A I was referred to Dr. Kim.
Q I believe it was Dr. Lynn Hoth; is that right?
A No.
Q So you don't remember who referred you to Dr. Kim?
A I do. I can tell you. Let's see. I know she is written in here somewhere. It was somebody at the Portland Adventist. Julie Crawford.
Q Julie Crawford. And who was Julie Crawford?
A She was the obstetrician and gynecologist that

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did my hysterectomy. She also -- both her and Kim, Dr. Kim, did both of the -- I mean they both did the hysterectomy and the bladder sling together.
Q It was at the same time?
A It was at the same time.
Q Okay. When was your first meeting with Dr. Kim?
A On the day that I met with Dr. Crawford about the hysterectomy.
Q And do you recall how long that first meeting was?
A No.
Q Can you tell me a bit about the discussions that you had with Dr. Kim?
A It was very interesting. I went in and she, you know, asked about my incontinence and I said, yeah. And she said, well, so I would like you to go in and go to the bathroom. And so I did. And then she said, so now we are going to see if there is any residual urine in your bladder. And so she did a catheter and took out an enormous amount of urine. And I was like, what? So anyway, she was like, yeah, you have got some issues here and so it looks like your bladder is sagging. And so she explained, you know, what was going on and I can't tell you

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exactly what was said but she said that, you know, the bladder sling was probably the best solution because it could just hold it. You know, it could hold the bladder up. And then she also talked about the vaginal walls may need work. She asked if I had problems defecating, and I said, not so much. And she said, well, you know, that might be an issue down the road. And so anyway, it was decided that those two procedures would benefit me.

Q So what do you mean by she thought that defecating might be an issue down the road?

A Well, I don't know. She just said, you know, sometimes when you have difficulty urinating, sometimes it is all the same muscle areas and so maybe your muscles are weakening and you need this mesh that would really help. So I don't think she treated the -- you know, for not being able to have a great bowel movement but that was part of the conversation.

Q Okay. And when you described that you went to the restroom and then she catheterized and there was an enormous amount of bladder left, did you ever feel or have any feeling that there was bladder --

A No.

Q -- or there was urine still in your bladder?

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A No. That is why it was so shocking to me. It really was a pretty shocking moment.

Q And did she ever discuss alternative treatments for you besides the bladder sling and the mesh implant?

A Not doing anything is what I remember.

Q Did she ever discuss any medications that you could take?

A No.

Q Did she ever discuss physical therapy or exercises that you could do?

A No.

Q But she did say that you could do nothing. Correct?

A Yes.

Q And why was that not an option for you?

A It was a pretty serious -- you know, the incontinence was very serious for me. I really felt like if there was something to be done, I was pretty excited about that. And she had been recommended to me from my friend. I mean, they were so -- they really felt like she was a great doctor and so I definitely had a lot of confidence in what she had to say.

Q And so her ultimate recommendation to you was

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the mesh implant and the bladder sling. Correct?

A Uh-huh, yes.

Q And did she provide any literature or patient brochures for you to read up on the bladder sling and the mesh implant?

A I assume she did but I don't remember them or -- I mean, I think she was very informative so I assume she did.

Q And I know you don't remember, but would it be your general practice to read through that literature that she gave you?

A Yes. I am definitely the person who reads the directions. I, you know, look at all the pictures, so, yes.

Q Do you remember anything that the literature said at all?

A I remember some pictures. You know, there was a picture and this is what it looked like I think. In my head that is what I see. That is all.

Q Did she diagram anything for you to help explain the procedure?

A She may have. I don't remember.

Q Did you ask Dr. Kim any questions about the procedure?

A I mean, I am sure I asked her a few questions,

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but I was really just waiting for her to tell me. I don't think I spent a lot of time asking a bunch of questions. I think I was asking like, well, what is the recovery time? Will this interfere with the hysterectomy that I am going to have, because that was my -- that was the most important procedure to me was the hysterectomy.

Q Why was that the most important?

A Because I had been bleeding my entire life. Okay? That was -- and I was anemic. It was just really a problem.

Q And what did she say that the bladder sling and the mesh implant -- what type of effect did she say that that would have on the hysterectomy?

A I believe there was no effect and it would be a great procedure to have at the same time. You are all in the same area. You know, it is like a good fit. And she told me at the time that both doctors would be doing each other's procedure. Like she would be doing the sling and then Dr. Crawford would be her backup and the other way around.

Q Did she ever tell you the name of the manufacturer of the mesh implant like during that conversation before the surgery?

A Not that I remember. The only thing I

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remember is there was a -- during one of my surgeries. I don't remember if it was the first or second there was a representative during my surgery. I had to sign a piece of paper that said that they could be there during my surgery.
Q And did that representative ever talk to you about anything?
A No.
Q Do you know if they just watched the surgery or what role they played?
A I have no idea, and the only reason I remember is because it just felt like what, ew. You know, I didn't -- I thought it was strange. So that is why I was thinking that maybe at that time they said, oh, this is a Bard representative but I -- that didn't settle in my head anywhere. I don't know.
Q You don't know who -- what company --
A I have no idea, none, none.
Q -- they were representing?
A Maybe it wasn't even that company. Maybe it was something else, some other instrument they were using. I have no idea.
Q And did you trust Dr. Kim's recommendation for the bladder sling and the mesh implant?
A Absolutely.

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Q And why is that?
A Well, she was recommended to me by this nurse that, you know, had worked with a lot of people. She is my neighbor. She worked a long time. She had seen this person. She had seen Dr. Crawford and Dr. Crawford had recommended this other woman and so I was just -- it was a great -- you know, a women's hospital, so, yeah, she was an expert. I absolutely trusted her.
Q And prior to the surgery, did you do -- did you evaluate Dr. Kim's skills at all on your own?
A I did not.
Q Had you talked to anyone who had surgery with Dr. Kim?
A Not before the surgery.
Q Did you talk to anyone after the surgery?
A My neighbor who had had a bladder sling and she actually had to have hers redone.
Q And Dr. Kim was the implanting physician on that?
A Uh-huh.
Q What was is the neighbor's name that you spoke with?
A Gayle Stephens.
Q Do you know why she had to have her bladder sling redone?
A I think she -- I think during her recovery she like made a quick move and like tore it or something. It was something like that. It was really her own -- kind of her own doing. I think that is what she told us.
Q Did you ever ask Dr. Kim about her qualifications to perform this surgery?
A No.
Q Did you ask her if she had ever implanted this product before and how many times she had implanted it?
A I don't believe -- no, I absolutely didn't ask her that, but I think she implied that she had done this surgery many times so she certainly didn't mention the product or anything like that.
Q Did she ever tell you what the success rate was of the product that she was using to implant?
A I assume so.
Q And you just don't remember what she said?
A I do not remember. I think it was favorable.
Q Did you do any of your own independent research online about the course of treatment that you were going to experience?
A I did not.

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Q Did you do any research specifically about the transvaginal mesh and the Bard product that you were going to be receiving?
A Absolutely not. I just want to say one more time the surgery I was most interested in was the hysterectomy. This other one was almost like a little picnic, you know, a little bonus.
Q Okay. And prior to the surgery, did Dr. Kim ever discuss the risks and benefits of the surgery with you?
A I am sure she must have. I just felt like she was very informative and very thorough and I just felt like it was going to be a great surgery, you know, really solve my issues. So I am sure she talked about it.
Q And do you remember any part of that conversation of what she said would be the benefits or the risks of the surgery?
A Well, the risks, I felt like they were just like surgery risks like anesthesia. You know, there would be a recovery period. So that is what I remember. I don't -- I mean, the risks, I am just going to say this: There was never anything about sexual intercourse being different or -- I mean, there is nothing like that that was mentioned. That

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would have been a super red flag for me.
Q So since you don't specifically remember, would you defer to your physician about your discussion and the general practice with informed consent?
MR. KUNTZ: Objection.
You can answer.
THE WITNESS: Can you repeat the question?
Q BY MS. COLLINS: So since you don't remember, would you basically trust your physician's testimony about the discussion about informed consent that she would have given you?
A Not at this point. I mean, I don't know. I will just say I don't know. Would I trust everything? I did then. I mean, I trusted everything she said then but now I would -- I would do everything different so...
Q What do you mean you would do everything different?
A I mean, I would never have had the mesh surgery because of all the complications that -- my life changing. If I would have read anything online or had any inkling that it would even have a chance of causing any of the issues that have plagued us, I

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would never have had the surgery.
Q You signed consent forms for the surgery. Correct?
A I am sure I did.
Q And would it be your general practice to read the forms before signing the consent forms?
A No.
Q And why not?
A The consent forms are usually given to you before surgery and the nurse usually tells you what it says. It usually says, you know, you are giving us permission to do the surgery or you are giving us permission to bill your insurance. That has been my experience.
Q So you wouldn't have read through the consent forms then?
A I would have perused them. Read them thoroughly, it is not likely.
Q So after your implant surgery, when was the next time that you saw Dr. Kim?
A After the bleeding, and like I said, I don't know what time -- what date that was. It was either the end of December or the beginning of January because my revision surgery was the end of January so it was either the beginning or somewhere just

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before that.
Q About a year later after the surgery?
A It was exactly -- almost exactly a year later.
Q Did you ever see her for a post-op appointment?
A Uh-huh.
Q And when was that?
A Four weeks, three weeks, six weeks after. I think there were two of them actually with her and Dr. Crawford.
Q And what was the prognosis at the post-op appointment?
A I think they said you are healing fine.
Q Were there any complications that they discussed with you?
A No.
Q Did you ever speak to Dr. Crawford about the procedure that Dr. Kim conducted?
A I never saw Dr. Crawford again after my hysterectomy and the six-week, so I have never talked to her about that.
Q And did you ever meet any Bard sales representatives?
A Not that I know of. Like I said, there was that one person who was there at the surgery, but I

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don't know at this point, I don't know anything, who they were, or even what product they represented.
Q Did they have a conversation with you at all before the surgery?
A I think it was an introduction so, no, conversation.
Q And did you speak to anyone else about your surgery?
A Anyone else?
Q Yeah. Like besides Dr. Kim and --
A Like to have the surgery or after the surgery?
Q Just after the surgery. Did you see any other doctors at all?
A I don't think so.
MS. COLLINS: Can we take a quick five-minute break?
MR. KUNTZ: Sure.
(Recess.)
Q BY MS. COLLINS: So now I am just going to talk to you about the implant surgery and your post implant condition. So you had the implant surgery on January 15th in 2008; is that correct?
A Yes.
Q Do you know if you were under general anesthesia?

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A Yes, I was.
Q And do you remember any discussions that you had with Dr. Kim after the surgery on the day of the surgery?
A I don't remember them. I know I did but...
Q Did you stay overnight in a hospital?
A Yes. I had the hysterectomy so that was the reason I stayed overnight.
Q Right, okay. And did you have any complications while you were in the hospital?
THE WITNESS: Do you remember if I had any -- I don't think so either. I don't know. Sorry. I know I can't ask him.
Q BY MS. COLLINS: Do you remember how long you stayed in the hospital?
A Two or three nights.
Q Were you given any discharge instructions?
A Oh, I am sure.
Q Do you recall if you were given separate discharge instructions for the mesh implant and bladder sling and the hysterectomy?
A I don't.
Q Would it be your general practice to follow the discharge instructions if they were given to you?

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A Uh-huh, absolutely.
Q And how were you doing after the surgery?
A Like right after the surgery? Well, I was really laid up. I mean, it took the full four weeks. You know, I thought I would get a lot of reading done. Oh, this is so wonderful. I will have all this time and really it was not like that at all. It was full recovery. There was a lot of -- I couldn't do anything. You know, just really tired, exhausted. Very difficult to move. Don was with me and my sister came and helped as well.
Q Were you on bedrest for most of that time?
A Uh-huh.
Q Do you recall how long you were on bedrest for?
A Well, I was off work for probably -- I think it was supposed to be six weeks, so it was like five or six weeks before I got a go-ahead to go back to work.
Q And did you have any urinary incontinence symptoms after the surgery?
A Not that I recall.
Q And did the surgery resolve your urinary incontinence issues?
A Yes.

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Q So you took that four to six weeks off of work. Correct?
A Yes.
Q And were you able to get through a full workday after that recovery period?
A I did. It wasn't easy but I did do it.
Q So did you have any issues -- what kind of issues did you have?
A Just tired. You know, I think just any normal issues you would have after surgery and getting back to full-time work.
Q What do you do for a living?
A I am a high school teacher.
Q Do you teach a certain subject?
A I teach -- I am a social studies teacher and I teach reading, writing, all kinds of things.
Q And besides that four-to-six-week gap before you returned to work, how long did it take you to return to your normal daily activities?
A Great question. I assume -- but I don't know. I am just assuming. So it didn't seem unusual, an unusual amount of time.
Q Would it be around the same time that you started work, do you think?
A It took me a little bit longer to really get

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my strength and my energy back.
Q And did you consider Dr. Kim to be a good physician?
A I did very much so.
Q And why did you stop seeing Dr. Kim?
A There was just no more need. I had the surgery. I had the revision surgery. I have not had any need to go back to see her. I have -- my incontinence has been taken care of.
Q And when was the last time you saw her?
A I can tell you. I have my last appointment, I believe, card. It was either 4/16 -- 4/16/09, 9 o'clock in the morning.
Q And you said that you did consider Dr. Kim to be a good physician?
A Yes.
Q Do you still consider her to be a good physician?
A Yes, I do.
Q Do you have any opinion of her and her skills at all?
A Well, I do. I think she did what she said she was going to do in that my incontinence is fixed.
Q And did you sue Dr. Kim at all?
A No.

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Q Why not?
A Why would I? I have no reason to sue her.
Q So we have talked about all of your complaints and your issues. Correct?
A Uh-huh.
Q So now I just want to talk about how they have affected your life. Your incontinence that you had for the reason that you had the mesh implant is resolved. Correct?
A It is resolved.
Q And have you regained your normal level of sexual activity?
A I have not. And you know what? I would take incontinence over this 100 times.
Q Prior to the mesh implant surgery, how often were you able to engage in sexual intercourse?
A Daily, up to daily. I mean, obviously it is probably not. It is probably two or three times a week.
Q And what about post surgery?
A Much limited. I mean, hardly ever.
Q Before the implant surgery were you able to achieve orgasms through sex?
A Absolutely.
Q And what about post implant?

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A Yes. I can still orgasm.
Q And what about your spouse who is making the loss of consortium claim? Is he still able to orgasm through sex now?
A If the sex happens, I assume, but it doesn't happen because it is too painful.
Q When was the last time you were able to engage in sexual intercourse?
A That is a great question. I have no idea. It has been months, months. And it was just as painful then as it was the last time. And I finally told him that time it was painful so it was kind of horrible.
Q And have you been able to express your love for your spouse in any other way besides just sexual intercourse?
A Absolutely. We love each other very much.
Q And is your marriage and relationship still strong?
A Yes.
Q And what other ways do you express your love and companionship for each other?
A By being companions, being friends, living in the same house, enjoying the same activities as in more walks.

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Q And has that changed since before the mesh implant to now after the mesh implant?
A I think it has taken a whole lot more effort. It has taken a lot of effort to emphasize those pieces because sexuality is a much easier way to express love and affection.
Q And would you say that this experience has caused you and your husband to grow closer to each other?
A No, I would not. I would say it has definitely not caused that.
Q Has it caused you to grow apart from each other?
A Yes. Thus the counseling.
Q And are there any hobbies or activities that you can no longer do as a result of your mesh implant?
A Let's see. I know there is a ton of things we have changed and some it is unconsciously, some of it is consciously. But anything that is too strenuous for me. I mean, Don is a very active person and so -- I mean, even too much digging in the garden can be really painful and exhausting so, I mean, it has curtailed it, yes.
Q And are you making a claim for lost wages?

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A No, I am not.
Q And when was the last time that you were able to take a vacation?
A We took a vacation Christmas before last. We flew to Hawaii.
Q And has your post-implant symptoms -- did that affect your vacation at all?
A We didn't go on any big, long hikes. We kind of sat around and read books and...
Q And what would you have probably done if you went on a vacation before the mesh implant?
A Sightsee a lot, done a lot more hiking and make kayaking. I mean, we have done a lot of things so...
Q And due to the mesh implant, you are not able to engage in activities like that?
A I would say due to my -- you know, just how my energy levels are lower. Is it because of the mesh implant? It feels like it.
Q And do you know anyone who works at Bard at all?
A I do not.
Q And have you ever spoken to anyone who has been employed at Bard? And I know that you don't know about that representative, so aside from that

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representative.
A I do not, no.
Q And other than your lawyers, with whom have you discussed this lawsuit?
A My sister.
Q What about other doctors or nurses?
A (Shaking head.)
Q Is that a no?
A It is a no. I am sorry. No.
Q And has anyone other than your attorneys ever told you that Bard has done anything wrong?
A Uh-uh. I do not know anything about Bard.
Q Has anyone ever told you that Bard was negligent?
A No.
Q Has anyone ever told you that the mesh implant --
A Except my lawyer.
Q Besides your lawyer, yes.
A Okay.
Q Besides your lawyer, has anyone ever told you that Bard -- the mesh implant and the bladder sling that you received was defective?
A No.
Q Okay. So other than your attorneys, has

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anyone ever told you that Bard did not give adequate warnings to their physicians?
A I haven't heard anything like that. I don't know.
Q Other than your attorneys, has anyone ever told you that Bard did not give adequate instructions to your physicians?
A No.
Q And have you shared with me all of your complaints about the Bard products that you received?
A I believe so.
Q So without telling me any specific conversations that you had with your attorneys, what did you do to prepare for this deposition today?
A I got time off work. We talked through e-mail a few times kind of setting up the appointment, just telling me where it would be, kind of how long it would last. We met last night. We met this morning.
Q So how many times have you met with your attorney to prepare for this deposition, not in total, just to prepare for today?
A We met in person twice.
Q And how long did those meetings last?

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A Three and one hour so four hours about.
Q And did you meet with anyone else to prepare for the deposition today?
A Like... no. I mean, no.
Q Did you review any documents on your own or with your attorney to prepare for the deposition today?
A No. Say that again.
Q Did you review any documents either on your own or with your attorney to prepare for today?
A Well, I did look at my fact sheet again to make sure I had it. I didn't know if I needed to bring it and so -- and I ended up not bringing it so I guess I didn't need it.
Q And did you look at any of your medical records at all?
A I have never seen my medical records.
Q At any time did you do any research about the issues in this case?
A (Shaking head.)
Q Is that a no?
A That is a no. I can -- yeah, that is a no.
Q Did you do any Google research about anything to do with this case?
A I just looked on -- in the newspaper today and

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they said that Bard was being bought by someone, so I didn't do any research but I did see it. And I was wondering if it was the same Bard so I didn't purposely do it. It was on the front page.
Q Did anyone instruct you on how to answer my questions today?
A No.
Q So I just kind of want to talk about your decision to file suit. When did you make that decision to file suit?
A My sister saw an advertisement on TV that talked about the transvaginal mesh and I didn't even -- anyway, she said, oh, my God, there was a list of all your symptoms. And she is the only one who knew my symptoms because we had talked about it. Don didn't know about it. So she actually called the company or called the number on the board and she said -- and then she told me about it. And so I decided -- and she knows how devastated it has been for my life -- devastating. And so I decided I would just call the number.
Q Do you remember when you first saw that commercial on the television?
A Maybe 2013 or '14. '14, I believe it was, 2014.

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Q And that was when you made the decision to file suit?
A Yeah, uh-huh.
Q And when did you first consult an attorney about this case?
A I can say it was close to that time, either '14 or '15, not too -- I don't know. Shortly after that.
Q Do you recall who you consulted with?
A I am sorry. I don't.
Q How did you find your attorney?
A From calling that -- from calling a number and somehow in that process.
Q Did you ever receive a call from a company who knew that you had been implanted with the transvaginal mesh and was offering to refer you to a lawyer?
A No, I don't believe so.
Q Do you know anyone else who filed suit against Bard?
A Uh-uh.
Q Did that neighbor that you spoke of earlier when you were talking about --
A No.
Q Did she ever file suit?

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A No, not at all, no. She really -- her issue was -- she doesn't have my issues. Her issues are different.
Q And do you know anyone else besides that neighbor we previously spoke about who was implanted with the Bard mesh product?
A Nobody.
Q Have you sold or assigned any interest in your right to recover any damages in this lawsuit to a third party?
A I don't even know what that would look like so I assume no.
Q Have you ever filed for bankruptcy before?
A No.
Q Have you ever filed a lawsuit before?
A No.
Q Have you ever been sued before?
A No.
Q Have you ever been arrested?
A No. Exciting. I told you I just got a speeding ticket though.
Q I know you said you drink occasionally so how often would you say that you drink?
A I would just say -- I mean, it goes off and on. Sometimes when I am really drinking heavy it is

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like once a weekend. One drink every weekend. That is when I am really swinging out.
Q Do you use recreational drugs at all?
A That is not Tylenol. Right?
Q Right.
A So, no, I don't.
Q Have you ever served in any branch of the military?
A Nope.
Q Have you ever served as a witness in a trial?
A Yes -- no. Oh, no. I am sorry. I am the jury.
Q Have you ever served on the jury?
A Yes.
Q Do you agree that it is important for a jury to consider both sides of the story before rendering a verdict?
A Absolutely.
Q And have you ever had any reason to obtain an attorney in the past prior to filing this lawsuit?
A Yes.
Q And what were those circumstances?
A Divorce, child custody.
Q Who did you hire at that time? Do you recall?
A Joel Sacks for one and Lois Albright.

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Q And that was for?
A Divorce and child custody.
Q So can you tell me a bit about your educational background?
A I have a master's degree. I have a bachelor's degree in secondary education and a master's degree in history and secondary education.
Q And where did you receive your bachelor's degree from?
A Western Oregon University.
Q And where did you receive your master's from?
A First of all, excuse me, Western -- it is the same college. They just changed names. Western Oregon University for both.
Q And do you hold any professional licenses or certifications?
A No, just the teaching degree.
Q And where are you currently employed?
A Neah-Kah-Nie High School in Rockaway.
Q And you said that you teach social studies and writing?
A Literacy. I also teach home ec. I have a variety of things on my plate.
Q And have you ever been terminated or voluntarily left a job due to any medical, physical,

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or psychiatric condition?
A Nope.
Q Have you ever filed a workers' compensation claim?
A Nope.
Q Are you currently on social security disability?
A No.
Q So how long have you and Don been married?
A 16 years.
Q Have you ever been separated from Don?
A No.
Q Have you ever considered divorce?
A No.
Q Did Don accompany you to your doctors' visits when you saw Dr. Kim or any of your doctors?
A Yeah. He has been there before. I am not sure if it was during that time but he has been there before. Actually I don't think he was there during that time. I think it was my sister who went with me.
Q To talk about the mesh implant?
A Uh-huh.
Q And you said that you have six children. Correct?

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A Yes.
Q What are their names?
A Cassy. Do you need them all, the full name?
Q Yeah. Cassy, and then their ages as well.
A Okay. Cassy is 40. Michael is 39. Kellieanne is 37. Rebecca is 36. Will is 34 -- 33. He will be not quite 34. And Thomas is 29.
Q And do any of your children live with you?
A No.
Q Did any of your children ever accompany you to your doctors' visits?
A No.
Q Do you have any grandchildren?
A Yes.
Q How many grandchildren do you have?
A Ten -- oh. No, ten.
Q And do you have any caretaking responsibilities for any family member?
A No.
Q Do any of your family or friends have medical training?
A My oldest daughter is a registered nurse.
Q That would be Cassy. Right?
A Cassy, uh-huh.
Q Do any of your family or friends have any

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legal training?
A No.
Q Have any of your family or friends experienced incontinence?
A Yes.
Q Who would that be?
A Coworkers older than myself so it is only said in passing.
Q And do you know if they ever had a repair involving mesh?
A None. None of them have.
Q Okay. That was a confusing question on my point.
A Yeah. None of them that I know have.
Q And have you ever had any family or friends who had a hernia repair?
A I believe -- I don't know. Not that I know of. I think my brother has but I don't know that for sure.
Q Do you know if mesh was used in the hernia repair?
A I don't know what is used in hernia repair. I am sorry.
Q Not just generally but just with his current repair.

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A I don't know. I have no idea.
MS. COLLINS: Okay. That is all the questions I have. Jeff, do you have any follow-ups?
MR. KUNTZ: I have one question.

EXAMINATION

BY MR. KUNTZ:
Q Is the first time that you realized that Bard might have created a defective product that led to your injuries is when you talked to an attorney?
A Yes. I had no idea any other time that there was anything wrong with the product. I thought it was me.
MR. KUNTZ: No further questions.
MS. COLLINS: No follow-ups.
(DEPOSITION ADJOURNED AT 11:53 A.M.)
(Signature Waived)
* * *
(NOTE: Untranscribed steno notes archived ten years on computer; transcribed English files archived five years on computer.)
* * *

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* * *

EXHIBIT INDEX

EXHIBIT	DESCRIPTION	PAGE
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EXHIBIT 2	Plaintiff Fact Sheet	11

(Attached hereto.)

CERTIFICATE

I, HEATHER L. FAIRLESS, a Registered Professional Reporter, Washington Certified Court Reporter, and an Oregon Certified Shorthand Reporter, hereby certify that said witness personally appeared before me at the time and place set forth in the caption hereof; that at said time and place I reported in stenotype all testimony adduced and other oral proceedings had in the foregoing matter; that thereafter my notes were transcribed through computer-aided transcription under my direction; and that the foregoing pages constitute a full, true, and accurate record of all such testimony adduced and oral proceedings had, and of the whole thereof.

Witness my hand at Portland, Oregon, this 27th day of April, 2017.

Heather L. Fairless
Oregon CSR No. 10-0418
Expires 9/30/17
Washington CCR No. 2842
Expires 10/01/17

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West Virginia Rules of Civil Procedure

Part V. Depositions and Discovery

Rule 30

(e) Review by Witness; Changes; Signing. If requested by the deponent or a party before completion of the deposition, the deponent shall have 30 days after being notified by the officer that the transcript or recording is available in which to review the transcript or recording and, if there are changes in form or substance, to sign a statement reciting such changes and the reasons given by the deponent for making them. The officer shall indicate in the certificate prescribed by subdivision (f)(1) whether any review was requested and, if so, shall append any changes made by the deponent during the period allowed.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

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EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

BECKY R. SMITH, et al.	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	Case No.
	)	2:15-cv-16402
C.R. Bard, Inc.,	)	
	)	
Defendants.	)	
	)	

DEPOSITION OF JIN-HEE KIM, M.D.
Taken in Behalf of the Plaintiffs

* * *

Thursday, June 13, 2019
Portland, Oregon

Reported by:
Shellene L. Iverson, CSR, CCR

INDEX

Deposition of: Jin-Hee Kim, M.D.

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NOTE: Deposition Exhibit Nos. 1 and 2 were marked prior to the commencement of the proceedings.

BE IT REMEMBERED THAT, pursuant to the Oregon Rules of Civil Procedure, the deposition of Jin-Hee Kim, M.D., was taken before Shellene L. Iverson, a Certified Shorthand Reporter, in and for the state of Oregon, commencing at the hour of 1:40 PM on the 13th day of June 2019, in the law offices of Hart Wagner, 1000 Southwest Broadway, 20th Floor, in the city of Portland, state of Oregon.

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Also Present:
Colin Sorensen, Videographer, Discovery Media

* * *

P R O C E E D I N G S

THE VIDEOGRAPHER: We are now on the record. My name is Colin Sorensen. I am a videographer for Golkow Litigation Services.

Today's date is June 13, 2019, and the time is 1:40 PM.

This is the video deposition of Dr. Jin-Hee Kim for the US District Court for the Southern District of West Virginia, Charleston Division.

We are located today in Portland, Oregon, in the matter of "Becky Smith vs. C.R. Bard, Incorporated."

Counsel, will you please introduce yourselves for the record, and our court reporter, Shellene Iverson, will swear the witness.

MS. SCARCELLO: Lindsey Scarcello on behalf the plaintiff.

MR. MANDELL: Mike Mandell on behalf of C.R. Bard, Inc.

MR. POTTER: Aaron Potter on behalf Dr. Kim.

///

///

Jin-Hee Kim, M.D.

being first duly sworn by the Certified Shorthand Reporter in the above cause, was examined and Testified as follows:

DIRECT EXAMINATION

BY MS. SCARCELLO:

Q. Hi, Dr. Kim. Good afternoon.

A. Hi.

Q. Will you please state your name for the jury.

A. Jin-Hee Kim.

Q. And, Dr. Kim, as I said, my name is Lindsey Scarcello. I represent Becky Smith and her husband, Don Mackie, in their product liability action against C.R. Bard.

You and I have never met or spoken before today; is that right?

A. Correct.

Q. And you understand that you're not a party to this lawsuit; is that right?

A. Yes.

Q. And you understand that Ms. Smith and her husband have not offered any criticism of your care or treatment in this lawsuit?

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A. Correct.
Q. Today I'll be asking some questions about your care and treatment of Ms. Smith from late 2007 to 2009, but before we get started, have you ever given your deposition before today?
A. Any deposition regarding this case?
Q. Not this case specifically, just at all.
A. Yes.
Q. Approximately how many depositions have you given?
A. One.
Q. Okay. And do you recall about when that was?
A. I believe it was June of 2018 although do not quote me on that.
Q. That's okay.
So were you a witness in that -- in that litigation?
A. I'm not sure I understand. Witness?
Q. Or how about you explain how -- your involvement in that case.
A. Similar deposition to this one.
Q. You said it was similar to this one?
A. Correct.
Q. Okay. So were you a treating physician in a case involving transvaginal mesh where an action had

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been brought against a manufacturer?
A. Yes.
Q. Okay. And were you a defendant in that case?
A. No.
Q. Okay. Have you ever provided expert witness testimony?
A. No.
Q. Do you recall the name of the manufacturer of the device involved in your 2018 deposition?
A. I do not.
Q. Okay. So other than your one prior depo regarding transvaginal mesh, you've never given any other depositions at all.
A. That is correct.
Q. And have you ever testified in court?
A. No.
Q. Okay. So you understand that the oath that you swore before we began this afternoon is the same oath that you would swear in a court of law?
A. Correct.
Q. And so you're under the same obligations to testify truthfully and fully here today as you would be if you were in a court of law. Do you understand?
A. Yes.
Q. And is there any reason that you can't provide

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full, complete, truthful testimony here today?
A. No.
Q. One ground rule that makes things a little bit easier for the court reporter is if we try to not talk over one another. So sometimes my question will linger or you will know where I'm trying to go and be inclined to answer, and other times I might interrupt you with my question and I will try not to do that. But it makes the court reporter's life a lot easier if we wait for the other person to be completely done talking before we start.
Can we both try to do that?
A. Yes.
Q. Great.
So before we get into Ms. Smith's care and treatment, let's first discuss your educational and professional background. Actually, strike that. Let's discuss the deposition notice which has been marked as Exhibit 1.
And if the court reporter can please provide that to the witness.
Have you seen this document before today?
A. Yes.
Q. Okay. And was it provided to you by your counsel?

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A. Correct.
Q. And there is a list of documents on the fourth page of that that we requested that you bring with you here today. What documents have you brought with you?
A. My CV.
Q. Okay. And there are documents related to your care and treatment of Ms. Smith that were collected as part of this litigation and were then provided to your attorney. Were those documents provided to you?
A. Yes.
Q. The medical records. Okay.
A. Okay.
Q. Have -- do you have any independent way to go out and get those medical records yourself?
A. No. This is preelectronic medical records; so they were all in storage, I believe.
Q. Okay. Okay. So we can set that aside and move to your CV which has been marked as Exhibit 2. If you could just give me an idea of your education and training to become a surgeon.
A. I went to medical school at UCLA and did my subsequent residency at UCLA as well.
Q. Any fellowships?
A. No.
Q. Okay. And so you're -- you're a urologist; is

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that right?
A. That is correct.
Q. So do you in your current practice see male and female patients?
A. Yes.
Q. In what specialties are you board certified?
A. Urology.
Q. Okay. So you don't have a board certification in female pelvic medicine and reconstructive --
A. I have a subspecialty certification in female pelvic floor and reconstructive surgery, yes.
Q. Okay. Have you done any research on behalf of any mesh manufacturer?
A. No.
Q. Have you been involved in any studies involving any mesh manufacturer?
A. No.
Q. Are you associated with any educational institutions?
A. No.
Q. In what states are you licensed to practice medicine?
A. Oregon.
Q. At what hospitals do you have privileges?
A. Adventist Medical Center, Providence Medical

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Center, Legacy Emanuel, Legacy Good Sam, Legacy Meridian Park.
Q. And you're currently in private practice; is that right?
A. That is correct.
Q. And how long have you been in private practice?
A. Can I look at my CV?
Q. Of course.
A. Since 2002.
Q. All right. In that time approximately how many transvaginal mesh products do you think that you implanted? That can just be a ballpark.
MR. POTTER: Are you asking how many different types of products or how many surgeries --
MS. SCARCELLO: How many --
MR. POTTER: -- in total for the various products?
BY MS. SCARCELLO:
Q. How many surgeries in total for the various products.
A. And are you including pelvic floor reconstruction and slings?
Q. Yes. You can break them up if you would like, but I am interested to know both.

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A. In the last 17 years?
Q. Uh-huh, yes.
MR. MANDELL: I'm going to object to relevance. It should be limited to 2008.
BY MS. SCARCELLO:
Q. You can go ahead and answer the question. I'm just trying to get an idea of your experience.
A. How about we just go by year because it will be easier for me to calculate in my head here.
Q. Okay.
A. And let's say I do -- and this is very rough, very rough estimation. Perhaps five to ten cases a month.
Q. For the last 17 years?
A. Yes.
Q. Okay.
A. Maybe less. I mean it's very rough.
Q. Right. That's -- I appreciate that. I'm -- I'm just trying to get a broad idea of your experience. So it's not -- certainly not a memory quiz.
And of those approximately how many were implanted for the treatment of pelvic organ prolapse?
A. Let's say roughly two per -- three per month, again, extremely rough estimate.

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Q. Fair enough. You said three per month; right?
A. Uh-huh.
Q. Okay. For the last 17 years?
A. Yes.
Q. Okay. And then does that mean that the remaining two to seven per month were slings?
A. Slings, yes.
Q. Okay. And then with Ms. Smith, it looked like she had both a POP kit and a sling implanted at the same time. Is that a common practice, or was that a common practice?
MR. MANDELL: Object to form.
THE WITNESS: I'm sorry?
MR. POTTER: Go ahead.
THE WITNESS: Yes.
BY MS. SCARCELLO:
Q. So there would be some overlap in the number of POP kits and midurethral slings; is that right?
A. That is correct.
Q. Okay.
MR. POTTER: They may at times put objections on the record --
THE WITNESS: Oh, I see. Okay.
MR. POTTER: -- for them to deal with later.

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THE WITNESS: Okay.
MR. POTTER: So as long as you understand the question, you're free to answer.
THE WITNESS: Okay. As long as you don't object.
MR. POTTER: We'll get there.
BY MS. SCARCELLO:
Q. Okay. So could you just briefly describe for the jury what pelvic organ prolapse is?
A. It's instances where either -- it could be either your bladder, could be uterus, it could be rectum is no longer being well supported by your pelvic floor and comes outside or comes down.
Q. And can you also briefly describe what stress urinary incontinence is?
A. It's the loss of urine with any kind of increased intraabdominal pressure, such as, coughing, sneezing, jumping, bending over.
Q. And could you also just provide a brief overview of your day-to-day practice, week-to-week practice, what that generally looks like.
A. I see patients in clinic every day. I have two half days of surgeries per week.
Q. Approximately how many of your patients are female?

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A. Again, this is a very rough estimate. 60 percent of my patients.
Q. Okay. So the remaining 40 percent are male?
A. Uh-huh. Or other.
Q. Or other.
With respect to your female patients, how many of them are experiencing pelvic organ prolapse? It can be a rough estimate.
A. 15 percent.
Q. And then what percentage of your patients are experiencing stress urinary incontinence?
MR. POTTER: You're talking female patients?
MS. SCARCELLO: Yes.
BY MS. SCARCELLO:
Q. Specifically, what percentage of your female patients experience stress urinary incontinence?
A. 25 percent.
Q. And so what other sorts of issues do you treat specifically in women besides pelvic organ prolapse and stress urinary incontinence?
A. Any kind of cancers that affect the -- the urinary system, such as, kidneys, bladder, ureter; dysfunctional voiding; stones, kidney stones.
Q. Okay. Is that all?

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A. Recurrent urinary tract infections. The list --
Q. I just don't -- I just don't want to interrupt you.
A. Yes. The list can go on.
Q. Okay.
A. Yes.
Q. Are you comfortable stopping there?
A. Yes.
Q. Okay. Thank you.
So can you explain just generally what it means for a physician to act as a preceptor on behalf of a medical device company?
A. It means that the company thinks you have enough experience that you can show or teach other physicians how to use their product.
Q. And have you worked as a preceptor?
A. I believe I have.
Q. And did you work for Bard as a preceptor?
A. I believe I have although my memory is fuzzy, but I think I did.
Q. Okay. Do you know approximately how many training sessions you provided on behalf of Bard?
A. I do not.
Q. Okay. Could you give me a rough estimate?

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A. It would be a complete guess.
Q. That's okay.
MR. POTTER: Well, she's not going to guess.
Either you have an estimate or you don't.
THE WITNESS: I do not have an estimate.
BY MS. SCARCELLO:
Q. You don't have an estimate?
A. I mean I do not recall.
Q. Okay. Do you think it was more than five?
A. I do not think so.
Q. Okay.
A. But again...
Q. Okay. So I have documents from Bard that indicate you started working in the preceptorship program in 2007. Does that sound right to you?
A. If that's the documents -- if that's what it says.
Q. Do you recall when you stopped providing training on behalf of Bard?
A. No.
Q. Do you recall why you stopped providing training on behalf of Bard?
A. Probably when the product went out of -- when Bard stopped making the product which I do not recall

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when that was.
Q. Okay.
A. You probably have a better answer than I do.
Q. Do you recall having an interview with a Bard representative on April 12, 2007, regarding your interest in Bard's preceptorship program?
A. I do not.
Q. Prior to that meeting -- do you have any reason to dispute that you met with a Bard representative on April 12, 2007?
MR. MANDELL: Object to form.
THE WITNESS: No.
BY MS. SCARCELLO:
Q. You previously mentioned that you would defer to the documents regarding your relationship with Bard. And so to that extent, I'm -- I'm -- that's why I was asking about that specific date.
MR. MANDELL: Object to form.
MR. POTTER: Object to form.
MR. MANDELL: Misstates her testimony.
MR. POTTER: Misstates her testimony.
But if you have an answer, go ahead.
MS. SCARCELLO: There wasn't a question.
MR. POTTER: Well, you can't just restate the witness' testimony inaccurately and then say it's

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not a question. I'm just objecting to the fact she never deferred to anything. She said if you have documents, she hasn't seen them. If you want to show her the documents and let her look at them and see if she has any reason to disagree with them, fine.
BY MS. SCARCELLO:
Q. I'm not going to show you the documents because I don't want to spend a whole lot of time on this.
But the -- Bard has internal documents that indicate that you had an interview April 12, 2007, and prior to that they sort of wrote up a profile of you. And in that profile it says that -- that you had 26 Avaulta cases to your credit and that you were, quote, experienced with the following Bard products: Anterior/Posterior Avaulta; Uretex TO; Pelvisoft, slash, Pelvicol; PelviLace TO.
Have you worked with those products before?
MR. MANDELL: Object to form. Lacks foundation.
MR. POTTER: Join.
Go ahead and answer if you can.
THE WITNESS: Could you restate the products again?

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BY MS. SCARCELLO:
Q. Sure. That's no problem. Anterior/Posterior Avaulta, Uretex TO, Pelvisoft/Pelvicol, and PelviLace TO.
A. I am familiar with the products. I am not sure I used the Uretex TO ever.
Q. Okay. Thank you.
You had used the Avaulta, though.
A. Yes.
Q. And then this same document says that you were, quote, working with the hospital to find a way for attendees to have hands-on privileges.
MR. MANDELL: Same objection.
BY MS. SCARCELLO:
Q. At that this time trainees are wel- -- at this time trainees are welcome as observers.
So there was a time when it sounds like your hospital was allowing you to provide preceptorship services to Bard, but the trainees could only observe. Does that sound right to you?
MR. POTTER: Object to form.
Go ahead and answer if you can.
MR. MANDELL: Join in the objection.
THE WITNESS: Yes.
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BY MS. SCARCELLO:
Q. Okay. Thank you. And then at some point the hospital allowed trainees to have hands-on experience; is that right?
A. I do not think they ever did but, again, I'm -- my memory is not -- this was over ten years ago.
Q. Fair -- fair enough.
Okay. Then I have some notes from the -- from the interview and, again, just briefly.
MR. POTTER: And since you're not going to share them with the witness, are these her notes, or are these the notes of the person who is apparently interviewing her?
MS. SCARCELLO: These are the notes of the interviewer. These are Bard's documents.
BY MS. SCARCELLO:
Q. So the notes indicate that you were asked whether it would be okay with you if on training days you only used C.R. Bard urological products. Are you okay with this? And the note indicates that you don't use other products.
So at this time in 2007, were you using exclusively Bard transvaginal mesh products?
MR. MANDELL: Objection. Lacks

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foundation.
MR. POTTER: Object to form. Foundation. Hearsay.
Go ahead and answer if you can.
THE WITNESS: I don't want to say I had a contract with Bard when I was only using their products. That is not true.
BY MS. SCARCELLO:
Q. Right. So I'm not trying to say you had a contract with them. What I'm asking about is, prior to becoming a preceptor for Bard, there was a conversation that was had with Bard in which the notes indicate that you said you use only Bard products. And I'm just wondering --
A. Uh-huh.
Q. -- if that conforms with your recollection.
MR. MANDELL: Same objections.
THE WITNESS: No.
BY MS. SCARCELLO:
Q. So you -- you think you used other non-Bard products for the treatment of POP and SUI?
A. I want to say yes. Yes.
Q. Okay.
A. But, again, I'm not -- yeah. My -- this is digging into my memory.

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Q. Right. I understand it was a long time ago. And I appreciate that -- you know, that nobody could be expected to have perfect recall. So that -- that is understood.
The notes also indicate that you were asked what is your signature and/or favorite repair, and it says No. 1 is her stone procedures. Do you know what that means?
MR. MANDELL: Same objection.
MR. POTTER: Join.
Go ahead and answer.
THE WITNESS: Kidney stones is what I'm assuming I meant.
BY MS. SCARCELLO:
Q. And so that was your signature procedure?
A. I do not believe I was ever asked a question of what signature procedure was. This was probably something they inferred from my -- again, not having access to the notes and not having seen what the actual notes say, but I would never use a word such as a "signature" procedure. So I believe that's a misnomer.
Q. Okay. Do you do a lot of kidney stone procedures?
A. Yes.

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Q. And is that probably a procedure that you performed the most around April 2007?
MR. MANDELL: Object to form.
THE WITNESS: It's, honestly, impossible to say. You're asking me to recall surgeries that I did over 12 years ago on a particular month, and it is impossible to say.
BY MS. SCARCELLO:
Q. I -- I understand that you don't have perfect recall, and I don't expect you to. I'm just asking in general if these things make sense to you or if they -- if it seems like that cannot possibly be true.
MR. POTTER: Well --
BY MS. SCARCELLO:
Q. So that's -- that's what I'm asking.
MR. POTTER: Object to form because you're using somebody else's notes that she didn't author that you won't show to her to ask her if those notes make sense to her on a conversation that she doesn't recall from more than 12 years ago.
So with that standing objection, if you can answer her questions, you're free to.
But can I have a standing objection so I don't have to keep --
MS. SCARCELLO: Yes.

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MR. POTTER: -- raising this every question?
MR. MANDELL: I'll join in that.
MS. SCARCELLO: That would be great.
THE WITNESS: Typically we do -- I do a lot of stone cases, yes.
BY MS. SCARCELLO:
Q. Okay. And then at this time it also says that slings were your No. 2 procedure. Is that --
A. If that's what I said, but, again, my recall is not perfect.
Q. Okay. Fair enough.
Then there are some internal messages about this -- this ability for preceptees to engage in hands-on training. And there's an e-mail from May 9, 2007, from a Bard physician training specialist that says, Initially we had a hold on Dr. Kim for contract pending the privileges. But you had prev- -- you prior to this May 2007 e-mail had received privileges. Does that sound right to you?
MR. POTTER: Hold on. Objection. You're not giving the witnesses context as to who the e-mail is to, who the e-mail is from, whether she received the e-mail. And I think you're confusing who is getting the privileges and then asking Dr. Kim to

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comment on it.
So if you want to show her the e-mail and ask her questions about that, she'll answer. But the way that you're doing it, it's not fair to the witness, and I don't know how she's expected to answer your questions.
With that objection, if you have any way of answering her question, you're free to do so.
MR. MANDELL: Join in the objection.
THE WITNESS: Was this an e-mail to me?
BY MS. SCARCELLO:
Q. No, it's not an e-mail to you.
A. Okay.
Q. And I'm not really even asking about the e-mail. You can forget the e-mail. I'm just asking if at some point your institution allowed for you to provide hands-on training to preceptees on behalf of Bard.
A. I believe I answered the question before -- yeah? -- whether --
MR. POTTER: Answer again.
BY MS. SCARCELLO:
Q. I don't recall your answer. I'm sorry.
A. Oh. Whether Bard -- whether my institution allowed nonprivileged physicians to have hands-on

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privileges. Is that what -- the question you're asking me?
Q. Allowed -- my question is whether your institution allowed you to provide hands-on training to preceptees in your capacity as a preceptor for Bard.
MR. MANDELL: Object to form.
THE WITNESS: And I answered this before. I do not believe my institution allowed -- they allowed observations. I do not think they allowed hands-on privileges. Then, again, my memory is not perfect.
BY MS. SCARCELLO:
Q. That's okay. I appreciate that.
Do you recall the amount that you were to be paid by Bard for training sessions?
A. I do not recall.
Q. The documents that I have been provided indicate that you were to be a paid of total of $1500 per day for on-site training sessions conducted at your institution. Does that sound right to you?
MR. MANDELL: Object to form.
MR. POTTER: Join.
THE WITNESS: If that is what the document says. Again, I do not recall.

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BY MS. SCARCELLO:
Q. Okay. And for a full day of training, that you were paid $2500 per day. Do you have any reason to dispute that?
MR. MANDELL: Same objection.
MR. POTTER: Objection. And I really don't see what the relevance is because she's already testified that the hospital didn't allow her to do the training. So it's just a hypothetical of what she was going to be paid, or are you asking her whether she actually received this money for training and she actually performed on behalf of Bard for this product?
MS. SCARCELLO: I -- you completely lost me. I -- I --
If you wouldn't mind just reading back the question.
I think we're pretty straightforward.
MR. POTTER: Well, here's my objection. You haven't established that she ever conducted training.
MS. SCARCELLO: She did at least -- she said she did probably five.
THE WITNESS: But I do not believe there were hands-on training.
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BY MS. SCARCELLO:
Q. Okay.
A. So there might have been observation as far as I can recall.
Q. Okay.
A. Yes.
Q. Fair enough.
MS. SCARCELLO: There's nothing to indicate to me that -- whether it was hands-on or not, that the payment was any different. And, regardless of that, I'm just trying to find out the extent of her relationship with Bard. That's it.
MR. POTTER: If you can answer what the extent of your relationship was with Bard back in 2007, go ahead.
THE WITNESS: That was the extent of my relationship with Bard.
BY MS. SCARCELLO:
Q. What was? That you were --
A. The -- what you were -- what you had just mentioned.
Q. The being involved in the preceptorship program.
A. Correct.
Q. Okay. And the $2500 per day honorarium sounds

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right to you?
MR. MANDELL: Object to form.
BY MS. SCARCELLO:
Q. Is that correct?
A. Again, if that is what the document says --
Q. Okay.
A. -- I'll not dispute it.
Q. Do you recall which products you used in your capacity as a Bard preceptor?
A. The Avaulta products.
Q. Did you also use the Align products?
A. Yes.
Q. And did you use both the Align and the Align TO devices?
A. Yes.
Q. Okay. And in January 2008, you implanted the Avaulta and the Align TO in Ms. Smith; is that right?
A. Yes.
Q. Okay. And do you recall if there were any trainees observing that procedure?
A. I do not recall. I do not recall.
Q. Besides Bard were you ever involved in any other company's preceptor programs related to transvaginal mesh devices?
A. I think I may have been involved with AMS but

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I have -- yeah. I don't know. I mean I think so.
Q. And was it also AMS transvaginal mesh devices?
A. Correct.
Q. And do you recall which one?
A. AMS has the Elevate product.
Q. And do you recall the time frame?
A. I do not.
Q. Okay. Do you recall receiving hands-on or practical training with the Avaulta and Align TO?
A. I don't recall specifically. Usually -- I have attended several cadaver labs, but I could not tell you time, dates.
Q. Prior to implanting the Avaulta in -- strike that.
Prior to the first time you implanted the Avaulta, do you believe that you attended a cadaver lab?
MR. MANDELL: Object to form.
MR. POTTER: Are you talking ever or with respect to your client?
MS. SCARCELLO: I said prior to the first time she -- she implanted an Avaulta product.
MR. POTTER: So ever.
THE WITNESS: I think so. But, again, I'm not sure of the time frame, but believe I did, yes.

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BY MS. SCARCELLO:
Q. Okay. And same question with regards to the Align TO. Do you think prior to the first time you implanted an Align TO device that you had attended a cadaver lab?
A. I think I did.
Q. Okay. And can you just give us a general idea of what is involved with a cadaver lab?
A. It's where you go to a place that has cadavers and you have -- perform procedures.
Q. And you perform them on the cadavers.
A. Correct.
Q. And do you typically just work with one cadaver, or do you practice the procedure multiple times?
A. Depends on the availability of the cadavers --
Q. Okay.
A. -- and how many the lab actually has.
Q. Okay. Do you recall with respect to the Avaulta or the Align?
A. I do not recall.
Q. And after your training with Bard, were you confident in your ability to perform the Avaulta and Align TO implant procedures?
A. Yes.

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Q. And so if Bard has taken the position that the plaintiff's injuries in this case are the fault of third parties including implanting doctors such as yourself, you would want to know that; right?
MR. MANDELL: Object to form.
MR. POTTER: Join.
THE WITNESS: Sure.
BY MS. SCARCELLO:
Q. And if Bard had blamed plaintiff's injuries on implanting surgeons in documents filed in this litigation and even during trials in open court, you would want to know that; right?
MR. POTTER: Object to form. She's not going to engage in speculation. If you want to show her a document that pertains to her care, she can answer. She's here as a fact witness. We haven't been provided any documents with respect to your litigation. And so you're asking her to speculate about something she couldn't possibly know about and then asking her a hypothetical question about it. We're not going to do that.
BY MS. SCARCELLO:
Q. My question is --
MR. POTTER: I know what your question is, but she's not going to --

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MS. SCARCELLO: I wasn't talking to you. I'm asking you her.
MR. POTTER: Okay.
MS. SCARCELLO: And if you could just reserve your objections to a form objection and either requesting that your witness doesn't answer or not, I would appreciate that because we only have limited time.
MR. POTTER: Well, I'll make the objections I think are appropriate. Why don't you ask your next question.
BY MS. SCARCELLO:
Q. My question is: If Bard blamed plaintiff's injuries on implanting surgeons in open court in these transvaginal mesh cases, is that something that you would want to know?
MR. MANDELL: Object to form.
MR. POTTER: Objection. Instruct the witness not to answer. Next question.
BY MS. SCARCELLO:
Q. Do you recall when and where you received any training on the Avaulta device?
A. No.
Q. Do you remember the number of days that you trained on the Avaulta device?

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A. No.
Q. Do you recall whether there was a didactic training provided on the Avaulta device?
A. I do not recall.
Q. Do you recall the name of the preceptor who did your training on the Avaulta device?
A. I do not recall.
Q. Do you recall whether you had observed an Avaulta implantation prior to your training on the Avaulta device?
A. I do not recall.
Q. Is it fair to say that, when you went to the professional education training with Bard, that this was your first time to get in-depth information about the Avaulta device?
MR. MANDELL: Object to form.
THE WITNESS: Do you have a date on that?
BY MS. SCARCELLO:
Q. No. I just wanted in general.
A. Oh.
Q. Would -- would attending a cadaver lab or a didactic be the first time that you would have received in-depth information about that device?
MR. POTTER: Object to form.
THE WITNESS: Probably.

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BY MS. SCARCELLO:
Q. Do you recall whether a PowerPoint presentation was provided?
A. Unfortunately not.
Q. Do you recall if you were provided with any materials?
A. I do not.
Q. Would you have assumed that the information that was being provided to you at these training programs was accurate, to the best of Bard's knowledge?
MR. MANDELL: Object to the form.
THE WITNESS: I would hope so.
BY MS. SCARCELLO:
Q. With respect to your training on the Align TO, do you remember the number of days that you trained on the Align TO?
A. No.
Q. Do you recall whether you did a didactic training?
A. No.
Q. Do you recall the name of your preceptor?
A. No.
Q. Had you ever observed an Align TO implantation prior to your training with Bard on the Align TO?

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A. I don't think so. I don't know.
Q. Is it fair to say that, when you went to the professional education training with Bard, that that was your first time to get in-depth knowledge about the Align TO?
MR. MANDELL: Object to form.
THE WITNESS: Probably.
BY MS. SCARCELLO:
Q. What, if anything, do you recall about the oral presentation on the Align TO?
A. I do not recall.
Q. And, again, did you assume that the information that was being provided to you by Bard about the Align TO at the professional education course was accurate to the best of Bard's knowledge?
MR. MANDELL: Object to form.
THE WITNESS: Yes.
BY MS. SCARCELLO:
Q. Did you assume that the risks that Bard knew about, especially the serious risks that they knew about, that were associated with the Align TO would have been presented to you as part of that presentation?
MR. MANDELL: Object to form. Lacks foundation.

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MR. POTTER: Object to form.
Go ahead if you can.
BY MS. SCARCELLO:
Q. You can answer.
A. Yes.
Q. Did anyone from Bard ever tell you that they -- that the company did no premarket testing regarding the adequacy -- the adequate effective pore size of the transvaginal mesh products?
MR. MANDELL: Object to form as irrelevant.
MR. POTTER: Join and foundation.
Go ahead.
THE WITNESS: Would you mind repeating the question?
BY MS. SCARCELLO:
Q. No problem.
Did anyone from Bard ever tell you that they did not do any premarket testing regarding adequate effective pore size for transvaginal mesh?
MR. MANDELL: Same objection.
MR. POTTER: Same objection.
THE WITNESS: No.
BY MS. SCARCELLO:
Q. Did anyone from Bard ever tell you that they

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did no premarket testing regarding polypropylene degradation?
MR. MANDELL: Object to form. Lacks foundation.
MR. POTTER: Join.
THE WITNESS: No.
MS. SCARCELLO: Would you all just like to have a standing objection to this line of questioning as well?
MR. MANDELL: Yes.
MR. POTTER: Sure.
BY MS. SCARCELLO:
Q. In fact, did anyone from Bard ever tell you --
MR. MANDELL: And is this limited to before her implant or at all times?
MS. SCARCELLO: My question is did anyone from Bard ever tell you, ever.
BY MS. SCARCELLO:
Q. So did anyone from Bard ever tell you that the manufacturer of the polypropylene that was used to create its transvaginal mesh products provided this medical application caution with the plastic? Quote, do not use this Phillips Sumika Polypropylene Company material in medical applications involving permanent implantation in the human body or permanent contact

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with internal body fluids or tissue.
MR. MANDELL: Object to form. Lacks foundation.
THE WITNESS: No.
BY MS. SCARCELLO:
Q. Is that something you would have wanted to know?
MR. POTTER: Hold on. I'm letting you ask whether anybody told her that. She's not going to give you a hypothetical answer when you present her with incomplete information here today; so on that basis I'm going to instruct her not to answer. If you want to try to correct the question, feel free.
MS. SCARCELLO: It's really not a hypothetical.
BY MS. SCARCELLO:
Q. My question is: Is that something you would want to know?
MR. MANDELL: Join the objection.
MR. POTTER: Well, she's not going to -- you haven't even provided foundation to her as to whether that exists or not. And then you ask her whether she would want to know something. I'm trying to help you so you can correct your question; otherwise, I'm just going to instruct her not to

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answer.
MS. SCARCELLO: So she can't answer whether she would like to know certain information?
MR. POTTER: Correct. She's here as a fact witness. If you want to ask her whether she was aware of that information, she'll answer it. She's not going to tell you hypothetically whether she would want to have known information that she's not getting complete context about for the deposition. That's my instruction.
MS. SCARCELLO: Then we'll -- we will just go through what all she didn't know.
MR. POTTER: Fine. It's your time.
BY MS. SCARCELLO:
Q. Did anyone from Bard ever tell you that its manufacturing process damaged the polypropylene material using heat, stress, and knitting?
MR. MANDELL: Object to form. Lacks foundation. Running objection.
MR. POTTER: I'm just going to have my standing objection.
MR. MANDELL: Same objection.
THE WITNESS: No.
BY MS. SCARCELLO:
Q. Did anyone from Bard ever tell you that they

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didn't do any premarket testing regarding matching the elasticity properties of the mesh with the properties of the female pelvis?
A. No.
Q. Did anyone from Bard ever tell you that they didn't do any premarket testing regarding deformation of the product when it's placed under stress?
A. No.
Q. Did anyone from Bard ever tell you that this deformation of the product when it's placed under stress can change the character of the transvaginal mesh device?
A. No.
Q. Did anyone from Bard ever tell you that there was no premarket testing to determine whether the mesh lacked structural stability?
A. No.
Q. Did anyone from Bard ever tell you that there was no premarket testing as to the mesh's elasticity?
A. No.
Q. Did anyone from Bard ever tell you that there was no premarket testing regarding the elongation characteristics of the mesh after being implanted in the human body?
A. No.

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Q. Did anyone from Bard ever tell you that there was no premarket testing regarding the mesh's inflammatory or foreign body response that causes intense scarification or scar plating?
A. No.
Q. Did anyone ever tell you that the mesh's inflammatory foreign body response can cause contraction of the tissues which creates pain?
A. No.
Sorry. My alarm just went off. I have to --
MS. SCARCELLO: We'll go off the record.
THE WITNESS: -- feed the meter.
THE VIDEOGRAPHER: We are off the record at 2:21.
(Brief recess taken at 2:21 PM. Resume at 2:31 PM.)
THE VIDEOGRAPHER: We are back on the record at 2:31.
MR. POTTER: And are we still on the list of questions that we have the standing objection to?
MS. SCARCELLO: Yes.
MR. POTTER: Okay.
BY MS. SCARCELLO:
Q. So, Dr. Kim, we're back on the record after a short break.
A. Yes.
Q. You understand you're still under oath?
A. Yes.
Q. Okay.
MR. MANDELL: Just for the record, I have the same standing objections.
BY MS. SCARCELLO:
Q. Did anyone from Bard ever tell you that there was no premarket testing that porcine dermis added to the Avaulta Plus product enhanced scar plate formation?
A. No.
Q. Did anyone from Bard ever tell you that there was no premarket testing regarding the blind passage of the trochars which could damage tissue as it passed and create a deformative load when the mesh is pulled through the surface?
A. No.
Q. Did anyone from Bard ever tell you that, prior to their product being placed on the market, Bard had no clinical evidence to support the efficacy and safety of its Avaulta Plus product?
A. No.
Q. Did anyone from Bard ever tell you that in

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physician training presentations Bard used one-year data from a physician who studied the Avaulta devices which quoted a 6.7 percent erosion rate but that that same physician conducted a three-year study which showed an erosion rate of 13.6 percent?
A. No.
Q. Were you advised by Bard that certain key opinion leaders had recommended and volunteered to do premarket randomized control trials as to the Bard Avaulta products but that Bard rejected the same?
A. No.
Q. Were you ever advised by Bard or any Bard representative that certain key opinion leaders had recommended and offered to do a multicenter post-market study on the Bard porcine products but that Bard rejected that?
A. No.
Q. Did Bard or any company representative ever advise you that one of Bard's leading mesh proponents had proposed that Bard conduct a study on persistent delayed healing and mucosal erosion seen in its products that had been reported by implanting physicians but that Bard refused to do so?
A. No.
Q. Did Bard or any company representative ever

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advise you that Bard had seen that its polypropylene mesh in its Avaulta products could cause shrinkage or contraction up to 30 to 50 percent?
A. No.
Q. Did Bard or any company representative ever tell you that certain Bard Avaulta preceptors and proctors began complaining about complications they were seeing with the Avaulta products and that Bard terminated those doctors' contractual relationships with Bard?
A. No.
Q. Is it fair to say that your knowledge of the risks and complications associated with the Avaulta products grew, and you learned a lot more as time passed?
MR. MANDELL: Object to form.
MR. POTTER: Object to form.
MS. SCARCELLO: I'll strike that. I will restate the question.
BY MS. SCARCELLO:
Q. Is it fair to say that over time your knowledge of the risks and complications with the Avaulta product increased?
MR. MANDELL: Object to form.
MR. POTTER: Object to form.

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THE WITNESS: I may still answer?
MR. POTTER: That means you can still answer if you can.
THE WITNESS: Sorry. Would you mind repeating the question?
BY MS. SCARCELLO:
Q. No problem.
Is it fair to say that your knowledge of the risks and complications associated with the Avaulta device grew and -- strike that.
Is it fair to say that your knowledge of the risks and complications associated with the device increased over time?
MR. MANDELL: Same objection. Lacks foundation.
MR. POTTER: Objection.
Go ahead.
THE WITNESS: I'm not sure that my -- that -- I mean, as I was using the product, my knowledge grew. Did I think it was more risky or -- than when I first used it? No, if that's the question you're asking me.
BY MS. SCARCELLO:
Q. Okay. Do you recall reviewing a document referred to as the instructions for use, or the IFU,

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back when you were using the Avaulta?
A. No.
Q. So you did not review the IFU?
MR. POTTER: Well, you asked her --
MR. MANDELL: Object to form.
MR. POTTER: -- if she recalled reviewing it. That's a different question.
Go ahead if --
THE WITNESS: I do not recall reviewing it.
BY MS. SCARCELLO:
Q. Do you typically review the IFU for a device at least once before you begin implanting it in your patients?
MR. MANDELL: Object to form.
MR. POTTER: Go ahead.
THE WITNESS: Is this the same as the package insert?
BY MS. SCARCELLO:
Q. Yes, yeah, uh-huh.
A. I will look at the package insert, yes.
Q. Okay. And you look at the package insert -- strike that.
Is it fair to say that you look at the package insert before you perform a procedure for the

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first time?
MR. MANDELL: Object to form.
THE WITNESS: No.
BY MS. SCARCELLO:
Q. Would you ever perform an implantation of a device without looking at the package insert?
A. Yes. If I knew enough about the product.
Q. Okay. Do you recall whether you looked at the package insert for the Avaulta at some point prior to January of 2008?
A. I do not recall.
Q. Do you recall whether you looked at -- I thought you were going to say something.
Do you recall whether you looked at the package insert for the Align TO prior to January 2008?
A. I do not recall.
Q. And just so I understand your testimony, you might not -- you don't recall the actual event of sitting down and looking at the insert, but do you think that it is likely that you looked at the Avaulta package insert at some point?
MR. MANDELL: Object to form. Misstates testimony.
THE WITNESS: Mostly what I care about is what's FDA approved. So I don't think I spent an

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inordinate -- you know, an inordinate amount of time looking at any -- any inserts.
BY MS. SCARCELLO:
Q. Okay.
A. But, again, I don't recall.
Q. Can you just kind of explain what a package insert is? the information that's included in it.
MR. POTTER: Object to form.
Go ahead if you can.
THE WITNESS: I believe it has indications for -- I mean, it would be helpful if I had a package insert in front of me so I could know exactly what it is. I believe it has indication for use and how to use the product.
BY MS. SCARCELLO:
Q. Umm --
A. I mean --
Q. I'm sorry.
A. Yeah.
Q. Does a package insert typically list risks associated with using a product?
MR. MANDELL: Object to form.
THE WITNESS: I don't know.
BY MS. SCARCELLO:
Q. Did any of your Avaulta implant patients

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post-implant develop permanent dyspareunia?
MR. MANDELL: Object to form.
MR. POTTER: Are you talking prior to her -- or during her care of Ms. Smith? She's not going to go off and testify about all the patients she had after your client's surgery.
MS. SCARCELLO: I'm just asking in general if -- if she has had any patients who have developed chronic dyspareunia after having an Avaulta device implanted.
MR. POTTER: Okay. Let me -- let me do it this way since you don't want to correct your question.
Go ahead and answer to the extent you can prior to the end of your treatment with Ms. Smith. For any time period thereafter, I instruct you not to answer.
THE WITNESS: So this is for a specific time period?
MR. POTTER: Yes.
THE WITNESS: I don't recall. I don't think so.
BY MS. SCARCELLO:
Q. Do you recall anything in the Avaulta or the Align TO package insert describing or instructing

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physicians in terms of how to remove mesh?
MR. MANDELL: Object to form.
THE WITNESS: No.
BY MS. SCARCELLO:
Q. When you were trained as a resident, were you trained on how to remove mesh?
A. We had removed mesh, yes.
Q. And approximately how many times did you remove mesh during your training?
A. During residency?
Q. Uh-huh, yes.
A. Now, this is digging way back. Perhaps ten times.
Q. And so if Bard had information in its possession regarding the advisability of undertaking an excision or removal surgery, would you have liked to have had that information available to you?
MR. MANDELL: Object to form. Lacks foundation.
MR. POTTER: Objection. Instruct the witness not to answer.
MS. SCARCELLO: I will pass the witness.
MR. MANDELL: Can we go off the record for a second? Take a quick break.
THE VIDEOGRAPHER: We are off the record

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at 2:41.
(Pause in the proceeding.)
THE VIDEOGRAPHER: We are back on at 2:42.

CROSS-EXAMINATION

BY MR. MANDELL:
Q. All right, Dr. Kim. My name is Mike Mandell. I represent C.R. Bard in this matter. This is the first time you've ever met or spoken with me; is that correct?
A. Correct.
Q. Other than for purposes of scheduling this deposition, no one from or representing Bard has ever contacted you about this lawsuit; correct?
A. That's correct.
Q. And you understand your deposition is being taken in your capacity as one of Ms. Becky Smith's treating physicians?
A. Yes.
Q. And specifically with relation with the Avaulta Plus Anterior and Align TO which was implanted in her to treat her SUI and cystocele on January 15, 2008; correct?
A. Yes.

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Q. Okay. And you were the surgeon that did that implantation; right?
A. Yes.
Q. Have you ever spoken with Ms. Smith about her lawsuit?
A. No.
Q. Have you ever spoken with any of her other doctors about her care prior to her 2008 surgery?
A. No.
Q. How about after the 2008 operation? Have you spoken to any of her doctors?
A. No.
Q. Discussion with anyone else other than your attorney in preparation for this deposition?
A. No.
Q. Other than medical records, did you re- -- did you review any other documents in preparation for this deposition?
A. No.
Q. And I'm just going to introduce as Exhibit 3, this is a notice of deposition.
(Deposition Exhibit No. 3 was marked.)
BY MR. MANDELL:
Q. Were you -- have you seen this before?
A. Yes.

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Q. It -- was it provided to you by counsel?
A. Yes.
Q. And rather than going through all the requests here, my understanding is you came here with your CV and the medical file you have for Ms. Smith; is that correct?
A. I don't even have the medical file.
Q. Okay. Well --
MR. POTTER: Pursuant to the agreement that you guys --
MR. MANDELL: Right.
MR. POTTER: -- agreed that you had her chart.
BY MR. MANDELL:
Q. Right. So you didn't -- you didn't produce any additional medical records because we had already produced her chart; is that correct?
A. That is correct.
Q. As far as -- are you -- are you a member of any urological organizations?
A. The American Urological Association.
Q. Okay. What about ACOG?
A. No.
Q. AUGS?
A. No.

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Q. Were you ever a member of AUGS?
A. Yes.
Q. When -- when were you a member?
A. I don't know.
Q. Okay. Now I want to focus a little bit on treatment prior to Ms. Smith's implant in 2008. So how many patients could you -- can you estimate you treated for SUI at that time in January of 2008?
A. That one month?
Q. No. Sorry. Up until that time in January 2008, how many patients had you treated for SUI?
A. Again, this is going to be an extremely rough estimate. Let's say ten a month.
Q. Okay. And you -- and when did you first begin -- what year did you first begin treating patients for SUI?
A. If we count residency -- do we want to count residency?
Q. Let's start with residency, yeah.
A. So I started my urology residency 1998.
Q. Okay. And then after residency that would be --
A. Until 2002.
Q. 2002. Okay.
And as part of your practice in 2008, did

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you use synthetic urethral slings to help treat SUI in your patient population?
A. Prior to 2008?
Q. And including 2008.
A. Yes.
Q. And how long had you been using synthetic urethral slings for? You know, how long had you been using them for before the 2008 surgery?
A. Just generic synthetic slings, not Bard related.
Q. Correct.
A. Since residency.
Q. Okay. So that would be since 1998; correct?
A. That is correct.
Q. And were you using anything before -- before that?
A. Before residency?
Q. Yes. Did you --
A. No, I was not.
Q. Do you know which products from residency to 2008 you had used as far as synthetic urethral slings?
A. We did not use a name brand kit.
Q. Do you know what technique you used for implanting synthetic urethral slings during that time frame from when you first started to January 2008?

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A. Used the retropubic approach.
Q. Did you also use the transobturator approach?
A. No. Because it was not available at the time of my residency.
Q. And then --
MR. POTTER: So -- just so you listen to the time period. He's not restricting his question to residency.
THE WITNESS: Okay.
MR. POTTER: He's saying from residency through 2008 --
THE WITNESS: Oh, I see.
MR. POTTER: -- when you did the surgery on Ms. Smith.
THE WITNESS: Was I using transobturator tapes?
BY MR. MANDELL:
Q. Yeah. So were you using both approaches, retropubic and transobturator approach?
A. Once the transobturator tapes came on the market, I pretty much stopped using retropubic.
Q. Okay. Was there a reason for that?
A. It's less complications with the transobturator and better for the patient with excellent results.

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Q. And as far as the synthetic slings that you used since residency to Ms. Smith's implant, in terms of the poly- -- polypropylene material used in each of these slings, did you notice any difference between other manufacturers' slings and Bard's?
A. I have not.
Q. Now, this case involves an Align TO sling. Do you have an estimate how many overall patients you implanted with an Align TO sling at the time of Mrs. Smith -- sorry -- Ms. Smith's surgery in January 2008?
A. So what is the time frame you're asking me about?
Q. So any time before 2008 if you can give me an estimate of how many Align TO slings you had implanted.
A. Honestly, the number will be just a complete random guess. I mean, it's probably not even accurate.
Q. I don't want you to guess; so if you can't, then that's fine.
A. Okay. I don't know.
Q. Do you know when you first started using the Align sling?
A. When did -- when did the Align sling come on the market?

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Q. That I don't know off the top of my head right here. So do you have a recollection of when you first started using the Align TO sling?
A. Can I say when it came on the market?
Q. Yes.
Prior to the invention of urethral slings, other surgical techniques were used to treat women with SUI; correct?
A. Yes.
Q. And what type of surgical techniques were used?
A. This was actually even before my time when they used either a Burch or Marshall-Marchetti.
Q. And have you ever used those surgical -- surgical techniques?
A. No.
Q. As far as your knowledge, did you learn about those techniques in medical school or residency?
A. By "these techniques" you mean?
Q. The Burch and the -- and the --
A. I did not learn because these were prior to my training.
Q. Okay. Do you know -- as far as those techniques, can you tell me what complications are

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associated with them?
A. Not personally because I never performed these procedures, but, typically, women can experience urinary retention, failure to treat the underlying condition.
Q. Would pelvic pain, vaginal pain be a risk of those procedures?
A. I would assume so.
Q. Dyspareunia as well?
A. Yes.
Q. And scarring?
A. (Nods head.)
Q. Is that a -- is that a --
A. Yes.
Q. So you would agree that pelvic pain, vaginal pain, dyspareunia, and scarring is a risk and potential issue associated with all pelvic surgeries?
MS. SCARCELLO: Object to the form of the question.
THE WITNESS: Pelvic -- surgeries as a rule can cause scar tissue, will cause scar tissue so yes.
BY MR. MANDELL:
Q. And when you say causing scar tissue, you relate that to also causing pelvic pain and

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dyspareunia as well?
A. It can.
Q. Now, of your experience with patients you've implanted slings with, what has been your overall experience with respect to their outcomes?
MS. SCARCELLO: Object to the form of the question.
THE WITNESS: Are we talking about transobturator tapes in particular?
BY MR. MANDELL:
Q. Yeah. We can -- well, we can just talk about synthetic urethral slings, midurethral slings. What has been your overall outcome with your patients?
MR. POTTER: Object to form.
Go ahead.
THE WITNESS: Good.
BY MR. MANDELL:
Q. And would you say the same with the -- with your use of the Align TO?
A. Yes.
Q. And focusing on the time before Ms. Smith's implant in 2008, did you offer nonsurgical treatments to your patients with SUI?
A. Yes.
Q. And what sort of techniques were those?

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A. Revolving around pelvic muscle therapy whether it be kegels at home or through actual physical therapists.
Q. And what had been your patients' experience with using those nonsurgical treatments?
A. Depends on the patients.
Q. How would you say it compared to synthetic midurethral slings?
A. Not as effective.
Q. Now, switching to pelvic organ prolapse, can you tell me how many patients you had treated for pelvic organ prolapse at the time of Ms. Smith's January 2008 surgery?
A. No.
Q. As part of your practice, did you use vaginal mesh -- mesh in the surgical repair of pelvic organ prolapse?
A. Yes.
Q. And how long had you been using mesh for treatment of pelvic organ prolapse?
A. Since residency.
Q. Okay. So, again, 1998; right?
A. Yes.
Q. How -- can you tell me how many pelvic organ prolapse surgical repairs you performed in your career

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by January 2008?
A. No.
Q. Can you tell me on average how many per year?
A. In general? I think we covered this before. I'm going to say five per month.
Q. Okay. I'm sorry if I -- if I -- if this has already been covered. I guess, let me specify how many -- if you can, tell me on average how many per year you performed pelvic organ prolapse surgical repairs with mesh.
A. I would say five per year -- per month.
Q. Per month.
And what approach would you use for that?
A. Vaginal approach.
Q. Okay. Did you ever use the abdominal approach?
A. No.
Q. And why not?
A. That is not part of my training.
Q. Now, with respect to PO- -- I'm going to refer to pelvic organ prolapse as POP sometimes.
With respect to POP repair, did you ever perform a primary repair as opposed to a repair involving a medical device like mesh implant before 2008?

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A. Yes.
Q. And what type of primary repairs had you performed?
A. Plication.
Q. What are some of the better known risks or complications with a native tissue repair for pelvic organ prolapse?
A. Mostly very high risk of recurrence.
Q. Would you agree that vaginally placed mesh to treat POP is a minimally -- minimally invasive surgery particularly when compared to other options such as native tissue repair?
MS. SCARCELLO: Object to --
MR. POTTER: Object to form.
MS. SCARCELLO: -- the form of the question.
MR. POTTER: Go ahead.
THE WITNESS: Depends what you mean by "native form."
BY MR. MANDELL:
Q. We can -- we'll skip this one.
Do -- do you consider -- do you consider a benefit of vaginal mesh products to treat POP that it is minimally invasive?
A. It's a little tricky question because it

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really depends on your definition of "minimally invasive." I mean minimally invasive to me means a procedure I can perform in the office without undergoing general anesthesia. So in that regard, no.
Q. Okay. I guess I was trying to compare it to these other forms of native tissue repair that existed before the mesh is what --
A. Uh-huh.
Q. -- I'm really getting at.
A. Okay.
Q. So compared to those, would you say a benefit was that it's not -- it's less invasive?
A. If you mean is it better to go in vaginally than through a big abdominal incision, then the answer is yes.
Q. Okay. And that was my question.
And what are some of the benefits of -- of vaginal mesh repairs -- let me ask you this: Is one of the benefits of vaginal mesh repairs is it can -- can be done under regional anesthesia?
MS. SCARCELLO: Object to the form of the question.
THE WITNESS: It can.
BY MR. MANDELL:
Q. Okay. And can it usually be done as an

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outpatient or overnight stay?
A. Yes.
Q. Have you noticed that, compared to other methods, it -- it has a lower causation of pain?
MS. SCARCELLO: Object to the form of the question.
THE WITNESS: I can't comment because I don't really use a lot of other -- don't use any other methods.
BY MR. MANDELL:
Q. Okay. So leading up to the 2008 implant with Ms. Smith, can you tell me what products for pelvic organ prolapse you used?
A. Prior to the Bard product?
Q. Yes. So -- so we -- we -- we know you used the Bard product in Ms. Smith, but prior to that what other brands of POP mesh had you used?
A. Prior to Bard I don't think I used a kit.
Q. Do you -- I mean, do you recall any other brands of -- of mesh products used for treating POP?
A. Yes. But not before the Bard product.
Q. Okay. You -- but you may have used other products. Is that my understanding?
A. Yes.
Q. And as far as your use of other products, did

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you find them to -- to all basically work in the same way as -- you know, as vaginal mesh products work for -- for supporting the POP?
A. Yes.
Q. And can you approximate how many patients you placed an Avaulta product for the repair of POP at the time of 2008?
A. No.
Q. In general what had been your experience with mesh products for the treatment of POP?
A. Good.
Q. And that would include your experience with using the Avaulta?
A. Correct.
Q. As far as nonsurgical options in 2008 and prior, did you offer nonsurgical treatments to patients with POP?
A. Yes.
Q. And what had been your patients' experience in using those nonsurgical treatments?
MS. SCARCELLO: Object to the form of the question.
THE WITNESS: Again, it depends on the patients.
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BY MR. MANDELL:
Q. Okay. What about someone with a Grade II cystocele like Ms. Smith had? Do you know what their experience was like with nonsurgical treatments?
MR. POTTER: Object to form.
MS. SCARCELLO: Object to the form of the question.
MR. POTTER: Go ahead if you can.
THE WITNESS: It is so dependent on the patient no matter what the grade of the cystocele is.
BY MR. MANDELL:
Q. Okay. And, well, let me just ask you more generally then. How would you compare experiences of your patients with nonsurgical treatment versus transvaginal mesh treatment for repair of POP?
MS. SCARCELLO: Object to the form of the question.
MR. POTTER: Join.
Go ahead if you can.
THE WITNESS: Again, it depends on the patients. I mean, certainly, those that don't want to undergo surgery will be happy if I offer them nonsurgical methods; so...
BY MR. MANDELL:
Q. In -- well, strike that.

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Have you ever used medical products made out of polypropylene other than Bard's Align and Avaulta products?
A. Yes.
Q. And you agree that polypropylene is suitable to use -- for use in humans as medical device implants?
MR. POTTER: Object to form.
THE WITNESS: As long as it is FDA approved.
BY MR. MANDELL:
Q. Okay. Now, you're familiar with the Align -- hold on one sec.
Now, you're familiar with the Align TO used to treat -- to treat SUI; right?
A. I am familiar with it.
Q. And you -- you can't tell me when you first started using it, but you certainly used it during the time frame from residency to Ms. Smith's implant in 2008; right?
A. Yes. Not the entire time frame.
Q. But somewhere in there.
A. Yes.
Q. And given your continued use of the Align, is it fair to say you were satisfied with the product at

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the time?
A. Yes.
Q. You obviously wouldn't continue to keep using it if you felt it wasn't giving the best possible results for your patients; right?
MS. SCARCELLO: Object to form.
THE WITNESS: That is correct.
BY MR. MANDELL:
Q. Is there something in particular you liked about the Align TO that you liked more than other mid -- midurethral slings that were available on the market?
A. No.
Q. Do you agree that as of September 2008 it was within the standard of care for a surgeon to select the Align urethral sling for treatment of SUI in appropriate patients?
MR. POTTER: Hold on.
MS. SCARCELLO: Object to the form.
MR. POTTER: This witness isn't going to give standard of care testimony either. So if you want to rephrase the question as to why she chose it or something, she can answer, but she's not going to give standard of care testimony.
///

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BY MR. MANDELL:
Q. Were you critical of any aspect of the design or function of the Align TO?
A. No.
Q. Now, focusing on the Avaulta Plus Anterior, you're familiar with that for the treatment of POP; right?
A. Yes.
Q. Is there something in particular you liked about the Avaulta Plus Anterior compared to other transvaginal mesh products that were available on the market at the time?
MS. SCARCELLO: Object to form.
THE WITNESS: I thought it was a good product that was relatively easy to use.
BY MR. MANDELL:
Q. And, again, given your continued use of that product up to 2008, is it fair to say you were satisfied with the product?
A. Yes.
Q. And, obviously, you wouldn't continue to keep using it if you felt it wasn't getting the best possible results for your patients; right?
MS. SCARCELLO: Object to form.
THE WITNESS: Yes.

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BY MR. MANDELL:
Q. Now, you made the decision to choose to use the Align TO and Avaulta Plus Anterior for Ms. Smith's January 2008 surgery; is that right?
A. That is correct.
Q. Okay. Was there a reason you -- or strike that.
Was there a reason you chose Bard products as opposed to a different product?
A. I wonder whether Bard may have been the only product available.
Q. And when you say "only product available," is that --
A. At the time.
Q. -- available at the clinic you were at?
A. No.
Q. Oh.
A. Period.
Q. Okay. Would it be fair to say that you chose to use the Align involved with Ms. Smith -- Smith based on your experience with the products?
A. Yes.
Q. Now, you agree that all surgeries carry certain risks; correct?
A. Yes.

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Q. And there's no procedure that is 100 percent effective for all patients; true?
A. Yes.
Q. And there's no guarantee of success?
A. Yes.
Q. You did not provide Ms. Smith with any guarantee of success with respect to her surgery; correct?
A. I do not provide guarantees.
Q. In general how do you become aware of potential risks of procedures that your perform with medical devices?
MS. SCARCELLO: Object to form.
THE WITNESS: Prior experience, experience of others.
BY MR. MANDELL:
Q. Medical school and residency, I presume.
A. That is correct.
Q. What about medical literature?
A. That as well.
Q. You try to keep up with the literature?
A. Yes.
Q. And that -- those prior experiences, medical school and residency, medical literature, that's how you educated yourself about the Align and Avaulta

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products?
A. Yes.
Q. Counsel previously discussed the instruction for use documents. You indicated that you had no recollection of reviewing those; so I presume that's not something you rely on when you decide to perform a procedure on -- on a patient. Rather, you're relying on your medical literature, training, and experience; right?
MS. SCARCELLO: Objection to the form of the question.
MR. POTTER: Join.
Go ahead.
THE WITNESS: Yes.
BY MR. MANDELL:
Q. Now, I want to just bring out the instructions for use for the Align. This will be Exhibit 4.
(Deposition Exhibit 4 was marked.)
MR. POTTER: Do you have another copy, Michael?
Thank you.
BY MR. MANDELL:
Q. So I know you indicated that you don't have a recollection of reviewing this document prior to Ms. Smith's surgery. Right?

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A. Correct.
Q. And so it's fair to say you didn't rely on this document when deciding to implant the Align TO in Ms. Smith?
A. Correct.
Q. Now, I -- I understand you didn't rely on this. I simply want to go through some of the warnings in it and determine whether or not you were aware of the possibility of those before using the Align. Okay?
A. Okay.
Q. So if you look at the second page. And it ends with Bates number 234 in the bottom right-hand corner. If you look at the section "WARNINGS," it says "The implant procedure and the instrumentation associated with the surgical placement of the Align TO Urethral Support System carry an inherent risk of infection and bleeding, as do similar" -- "similar urological procedures."
Do you see that?
A. Yes.
Q. And I'm presuming that's something you were aware of prior to using the Align product on Ms. Smith.
A. Yes.

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Q. Okay. So now under "ADVERSE EVENTS," there's several adverse events listed here. And I'm just going to go through the exercise of reading them to you and asking you if you knew about them before implanting the Align in Ms. Smith. Okay?
The first one here says that -- well, let me read this. "Complications associated with the proper implantation of the Align TO Urethral Support System may include, but are not limited to:
"Postoperative hematoma, which may occur following the implant procedure."
Were you aware of that before Ms. Smith's 2008 surgery?
A. Yes.
Q. It says "Temporary urinary retention, bladder outlet obstruction, and voiding difficulties associated with over-correction/too much tension placed on the mesh sling implant."
Were you aware of that before her 2008 implant surgery?
A. Yes.
Q. It says "Perforations or lacerations of vessels, nerves, bladder or any viscera, which may occur during introducer needle passage."
Were you aware of that before her 2008

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surgery?
A. Yes.
Q. And then, finally, it says "Transitory irritation at the operative wound site, which may elicit a foreign body response that leads to inflammation, infection, or erosion of the implant."
Were you aware of that before her 2008 surgery?
A. Yes.
Q. Okay. And is it fair to say these adverse events that I just listed are -- are all risks of midurethral slings?
A. Correct.
MS. SCARCELLO: Objection to the form of the question.
BY MR. MANDELL:
Q. And would it be fair to say that those risks -- those risks, excluding the erosion, are risks for all pelvic surgeries whether or not you use mesh?
MS. SCARCELLO: Object to the form of the question.
BY MR. MANDELL:
Q. Actually, let me strike that. It was confusing.
And -- and, again, these risks are not

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unique to the Align; is that correct?
A. That is correct.
Q. And -- and you agree that infection could result in pain?
A. Correct.
Q. Inflammation could result in pain?
A. Yes.
Q. Scarification and contraction would result in pain?
A. Yes.
Q. And mesh erosion, extrusion, and migration could result in pain?
A. Yes.
Q. And you were aware of all of that before Ms. Smith's 2008 implant; right?
A. Yes.
Q. Now I'm going to introduce as the next exhibit the IFU for the Avaulta Plus. This will be Exhibit 5.
(Deposition Exhibit No. 5 was marked.)
BY MR. MANDELL:
Q. And I know this is not the most fun thing to do, but I'm going to go through the same exercise with you.
You, again, don't have a specific recollection of reviewing this IFU before implanting

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the Avaulta and in Ms. Smith in 2008; right?
A. Correct.
Q. And you didn't rely on this document in determining to prescribe the Avaulta Plus Anterior in Ms. Smith in 2008; is that correct?
MS. SCARCELLO: Object to form.
THE WITNESS: Correct.
BY MR. MANDELL:
Q. Understanding you didn't rely on this document to make any medical decisions, I just want to go through some of the adverse events listed here and determine whether you were aware of them before Ms. Smith's implant. Okay?
A. Okay.
Q. Now, it says here on page Bates No. AVA ending with 310 -- do you see that?
A. Yes.
Q. And do you see where it says "ADVERSE REACTIONS"?
A. Yes.
Q. Okay. It says "Potential adverse reactions are those typically associated with surgically implantable materials, including hematoma, seroma, mucosal or visceral erosion, infection, inflammation, sensitization, dyspareunia, scarification and

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contraction, fistula formation, extrusion and recurrence of vaginal wall prolapse."
Did I read that correctly?
A. Yes.
Q. And were you aware of all of those things before Ms. Smith's implant in 2008?
A. Yes.
Q. And you were -- to clarify, you were aware of those being risks before Ms. Smith's implant in 2008; correct?
A. Yes.
Q. And then it says, "Perforations or lacerations of vessels, nerves, bladder, bowel, rectum, or any viscera may occur during needle passage."
Did I read that correctly?
A. Yes.
Q. And, again, you were aware of that -- those risks before Ms. Smith's implant surgery in 2008; right?
A. Yes.
Q. Okay. Now, going on to the next page here, which ends in Bates Label 311, you'll see "Implantation Technique for the Avaulta Plus Biosynthetic Anterior Support System." Do you see that?

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A. Yes.
Q. And then I just want to flip to the next page and just focus on No. 10. And it says "The mesh should be sufficiently anchored to stabilize it during tissue ingrowth. Additional sutures may be used to secure the mesh tension-free. Anchoring points should be positioned at least 1 [centimeter] from the edge of the mesh. After desired positioning is complete, trim all ends of the mesh arms below the level of the skin and close incisions."
You were aware of this instruction before the implant with Ms. Smith in 2008?
A. Yes.
Q. And it says here "Caution: Excessive ten-" -- "Excessive tension [could]" -- "should be avoided on the mesh suture attachment points to account for wound shrinkage during the healing process."
You were aware of that tension concern before the implant in Ms. Smith in 2008; correct?
A. Yes.
Q. Okay. Now, looking back at that "ADVERSE REACTION" section I read to you, would you agree that, with the exception of the erosion, extrusion mentioned, all the other adverse reactions mentioned here are possible adverse events with surgery in

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the -- in the pelvic region?
MS. SCARCELLO: Object to form.
THE WITNESS: Yes.
BY MR. MANDELL:
Q. And they're present in surgery to repair POP with or without mesh; correct?
MS. SCARCELLO: Object to form.
THE WITNESS: Again, besides the mesh erosion and passage of needles, yes.
BY MR. MANDELL:
Q. Okay. And with -- with respect to all of the adverse reactions that we covered, would you agree that all transvaginal mesh to treat POP have the same similar risks listed here?
MS. SCARCELLO: Object to form.
THE WITNESS: Yes.
BY MR. MANDELL:
Q. And these risks are not unique to the Avaulta; correct?
MS. SCARCELLO: Object to form.
THE WITNESS: Correct.
BY MR. MANDELL:
Q. Okay. Now I just want to briefly -- you can put that aside now. I just want to briefly talk about some of the adverse reactions in a little more detail

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with you as they relate to both the Avaulta Plus and Align products. Okay?
The risk of dyspareunia is not unique to surgery using vaginal mesh, is it?
MS. SCARCELLO: Object to form.
BY MR. MANDELL:
Q. To pelvic surgery.
A. It is not.
Q. And what is dyspareun- -- I think you described it earlier, but just in case, what is dyspareunia for the record?
A. I actually did not describe it, but I will do so now. Pain with sex.
Q. Thank you.
Dyspareunia is a potential known complication with native tissue repair that does not use vaginal mesh; is that true?
A. Yes.
Q. And you agree that any pelvic surgery carries a risk of dyspareunia?
A. Yes.
Q. In your practice is dyspareunia an extremely common complaint among women?
A. No.
MS. SCARCELLO: Objection.

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BY MR. MANDELL:
Q. You -- you were aware of the risk of dyspareunia prior to performing surgery with the Align and Avaulta on Ms. Smith; correct?
A. Yes.
Q. And you're aware of dyspareunia being a short-term and long-term, or chronic, risk prior to Ms. Smith's implant; correct?
A. Correct.
Q. Now, focusing on pelvic and vaginal pain. The risk of pelvic and vaginal pain is not unique to surgery using vaginal mesh, is it? And I'm sorry. I should specify pelvic surgery.
A. No.
Q. And pelvic and vaginal pain is a potentially known complication with native tissue repair that does not use vaginal mesh; right?
A. Yes.
Q. You were aware of the potential risk of pelvic and vaginal pain prior to performing surgery with the Align and Avaulta on Ms. Smith; correct?
A. Yes.
Q. And you were aware of the pelvic and vaginal pain being a short-term and long-term risk, or chronic risk, prior to Ms. Smith's implant; correct?

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MS. SCARCELLO: Objection.
THE WITNESS: Yes.
BY MR. MANDELL:
Q. Okay. Now, we already discussed that prior to the mesh surgery of Ms. Smith you were aware of mesh erosion and extrusion; correct?
A. Yes.
Q. As well as mesh migration; correct?
A. Yes.
Q. And prior to Ms. Smith's 2008 implant, you were also aware that such risks of erosion, extrusion, migration may cause chronic inflammation?
A. Yes.
Q. And may cause chronic pain?
A. Yes.
Q. And could cause bleeding?
A. Yes.
Q. These are all known risks for any surgery involving vaginal mesh; correct?
A. Yes.
Q. Okay. Risk of vaginal scarring is not unique to -- to a surgery -- to pelvic surgery using vaginal mesh, is it?
A. No.
Q. Vaginal scarring is a potential known

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complication with native tissue repair that does not use mesh; right?
MS. SCARCELLO: Object --
THE WITNESS: Yes.
MS. SCARCELLO: -- to form.
BY MR. MANDELL:
Q. And agree that any pelvic surgery carries a risk of vaginal scarring?
A. Yes.
Q. And you were aware of the potential risk of vaginal scarring prior to performing the surgery of the Align and Avaulta in Ms. Smith; correct?
A. Yes.
Q. And you were aware that scarring could lead to pain and sexual pain both in the short term and long term prior to Ms. Smith's 2008 implants?
A. Yes.
Q. The same would be true about ban- -- banding as a risk?
A. Yes.
Q. Before the Align and Avaulta, you knew that you would be implanting a foreign body into Ms. Smith; correct?
A. Yes.
Q. And you learned about the body's inflammatory

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response to foreign materials during medical training; right?
A. Yes.
Q. Before using the Align and Avaulta in Ms. Smith, you knew that an inflammatory reaction to mesh could occur; right?
A. Yes.
Q. Any patient can have an idiosyncratic reaction to an implanted material; is that true?
A. Yes.
Q. And we just went over the IFU for Bard's product that states that an inflammatory adverse reaction is possible; right?
A. Yes.
Q. And that is consistent with your understanding at the time you used the Align and Avaulta in Ms. Smith; correct?
A. Yes.
Q. Do you agree that inflammation is a normal part of the healing process?
A. Yes.
Q. Expected after surgery?
A. Yes.
Q. That the formation of scar tissue is a normal and expected part of the healing process?

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A. Yes.
MS. SCARCELLO: Object to form.
BY MR. MANDELL:
Q. Do you agree that contracture is a risk for all vaginal mesh procedures?
MS. SCARCELLO: Object to form.
THE WITNESS: Yes.
BY MR. MANDELL:
Q. And you knew this before Ms. Smith's 2008 implant procedures; right?
A. Yes.
Q. So having now reviewed the Align and Avaulta IFUs, do you feel that the instructions for use that accompanied those Avaulta and Align products were adequate at the time of Mrs. Smith's 2008 implant?
MS. SCARCELLO: Object to form.
MR. POTTER: Object to form.
To the extent that you had an opinion back at the time, you can answer. You're not going to do a retrospective, new, present-day opinion.
THE WITNESS: Correct. Yes.
BY MR. MANDELL:
Q. And at the time of Ms. Smith's implant surgery, did you feel you knew enough about the Align and Avaulta Plus to make an informed decision about

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whether to use the product on Ms. Smith?
MS. SCARCELLO: Object to form.
THE WITNESS: Yes.
BY MR. MANDELL:
Q. And at the time of Ms. Smith's implant, did you feel you knew enough about the Align and Avaulta Plus to make an informed decision about how to use the products with Ms. Smith?
A. Yes.
MS. SCARCELLO: Object to form.
BY MR. MANDELL:
Q. Now, I just want to be clear. You didn't rely on any materials from Bard in making your determination to use the Align and Avaulta on Ms. Smith; correct?
MS. SCARCELLO: Object. Object to the form of that question. Misstates her testimony.
THE WITNESS: Okay. Say that again.
BY MR. MANDELL:
Q. Yeah. Did you rely on any materials from Bard in making your determination to prescribe and implant the Align and Avaulta into Ms. Smith?
A. No.
Q. At your office in 2008, did you have any Bard-specific pelvic mesh literature or brochures for

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patients?
A. I may have.
Q. Do you -- you don't recall one way or the other?
A. I don't -- no.
Q. So if I asked you what those brochures would say, you wouldn't be able to provide that; is that correct?
A. No.
Q. I want to go to the medical records. I believe that was Exhibit --
MS. SCARCELLO: Not entered as an exhibit yet.
MR. MANDELL: Oh, okay. Can we go off the record for a second? Take a quick break.
THE VIDEOGRAPHER: We are off the record at 3:20.
(Pause in the proceedings.)
(Deposition Exhibit No. 6 was marked.)
THE VIDEOGRAPHER: We are back on the record at 3:22.
BY MR. MANDELL:
Q. So, actually, before I go into these medical records, I wanted to address something opposing counsel asked you earlier. She kept asking has anyone

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from Bard told you "X," "Y," "Z," or -- or that. Do you recall her -- her continual questions about whether anyone from Bard told you something?
A. Yes.
Q. And those seemed to relate to studies about mesh, key opinion leaders, things of that nature; is that correct?
A. Yes.
Q. So have you seen any support for any of those questions counsel asked you about?
MS. SCARCELLO: Object to the form of the question.
THE WITNESS: I'm not sure what you mean by "support."
BY MR. MANDELL:
Q. Have you seen any documents supporting any of the questions that counsel asked you about?
MS. SCARCELLO: Object to form.
THE WITNESS: No.
BY MR. MANDELL:
Q. So you have no idea about the truthfulness of those statements that -- that counsel was asking you; is that correct?
A. That is correct.
Q. And so, obviously, they don't have an effect

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on your decision in 2008 to implant the Avaulta Plus and Align TO in Ms. Smith; is that correct?
MS. SCARCELLO: Object to form.
MR. POTTER: Object to form. I just want to make sure I understand. You're asking her whether all of those --
MR. MANDELL: Right.
MR. POTTER: -- hypothetical statements that counsel asked, whether that would have then affected her decision-making?
MR. MANDELL: That they -- since she doesn't know the truthfulness of those statements, they obviously have no impact on her decision in 2008.
MS. SCARCELLO: Well, but -- and she can't go back in time. That's why they don't have --
THE WITNESS: Well, I already answered that I would not -- I was not aware of any of those things that -- that opposing counsel from you told.
BY MR. MANDELL:
Q. Okay.
A. So I --
MR. POTTER: So I want to be consistent here with both of you.
MR. MANDELL: Right.
MS. PINTO: She's not going to take

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hypothetical information given to her today and tell either of you what she would have potentially done in 2008 with that information.

MR. MANDELL: Okay.

MR. POTTER: She's already testified nobody told her any of that information.

MR. MANDELL: Okay.

THE WITNESS: I have no information from what the opposing counsel had said.

BY MR. MANDELL:

Q. All right. And so we'll just leave it at that, that you agree that you don't know the truthfulness of any of those statements. Correct?

MS. SCARCELLO: Object to form.

THE WITNESS: Since I wasn't -- testified that I did not -- was not even aware of those so that's where I stand.

BY MR. MANDELL:

Q. So you don't know the truthfulness about them; is that correct?

MS. SCARCELLO: Object to form.

BY MR. MANDELL:

Q. If you're unaware.

A. I was unaware.

Q. One of the statements she asked you is if Bard

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ever told you if mesh -- mesh can elicit a foreign body response that could cause pain. We just talked about that; correct?

A. Yes.

Q. And although you're not aware of anyone from Bard telling you that, you were aware of that before the 2008 implant in Ms. Smith; correct?

MS. SCARCELLO: Object to the form of the question.

BY MR. MANDELL:

Q. I can -- I can repeat the question.

A. Yes. Actually, I don't recall the initial question, what the wordage was; so...

Q. So let me just say this. You were aware that mesh could cause a foreign body response in a patient, and that would, in turn, cause pain before Ms. Smith's 2008 implant; right?

A. Yes.

Q. All right. So going to the medical records now, these are Exhibit 6. And these are Bates -- Bates labeled from 1 to 54. Now, were these records prepared and maintained by your office in the ordinary course of business at or near the time of the date on the records?

A. Yes.

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Q. And fair to say that you try to put down everything that is pertinent to your findings on the date of a patient's visit or op- -- operation?

A. Yes.

Q. And when you create records, you try to be accurate and complete; right?

A. Yes.

Q. Okay. So if we can go to page 35, this appears to be the first time that Ms. Smith comes to Urology Clinic.

A. No, it's not.

Q. Okay. Do you know the first time, then?

A. Page 12.

Q. Page 12. So this is dated 11/30/2007 and the other record was dated -- on page 35 was dated 11/15/2007. That's why I was assuming it was the first --

A. No. This was the records, if you looked at page 39, by Dr. Julie Crawford who was the gynecologist.

Q. And is she not part of your -- your clinic?

A. No.

Q. I see. Sorry about that.

So -- so you were cc'd on Ms. Crawford's record here. It shows that on page 39; correct?

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A. Yes.

Q. And then presumably it looks like she recommended her to go see you -- Ms. Smith to go see you, and that's when you see her on page 12 here on 11/30/2007; is that right?

A. That is correct.

Q. Okay. Do you know if Ms. Smith provided you with -- with -- you or your clinic with any of her previous medical records?

A. Besides what she filled out for us in the clinic.

Q. Okay. If there were any previous medical records, they would be in this file; right?

A. That is correct.

MR. POTTER: Are you including the record from 11/15 that you just identified?

MR. MANDELL: Right.

BY MR. MANDELL:

Q. So, I mean, if there were any other previous records, they would be in this file we're looking at, Exhibit 6.

A. Yes.

Q. Okay. So looking at page 12, this is 11/30/2007. Can you summarize why Ms. Smith visited you and your diagnosis?

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A. The patient was suffering from stress urinary incontinence as well as heavy menses.
Q. And so just go into that a little bit further. She complained to you about stress incontinence; right? What symptoms was she having related to stress urinary incontinence?
A. She was having leakage with coughing and sneezing.
Q. And it looks like it says here that at some point she was having to change pads two times a day; is that correct?
MS. SCARCELLO: Object to form.
THE WITNESS: Yes.
BY MR. MANDELL:
Q. Other than Ms. -- Ms. Smith's self-reporting here, did you run any tests on her related to her complaint of SUI?
A. Just a urinalysis.
Q. And what did -- what did that test conclude or entail?
A. Just dipping your urine in a urine dipstick.
Q. Okay. And you believed Ms. Smith was a good candidate for the sling, the Align TO placement at this time; correct?
A. Yes.

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Q. And why did you believe that?
A. Because of her symptoms.
Q. Okay. And -- and you're referring to her leaking symptoms; correct?
A. That's correct.
Q. And then on page 13, you indicate here that she has a Grade I to II cystocele.
A. Yes.
Q. And what is -- what is a cystocele exactly?
A. Cystocele is the prolapse of the bladder.
Q. And what is a Grade I to II?
A. Usually -- we have a grading system of I through IV where IV is complete prolapse of the organ outside of the vaginal introitus. And I, II, III, is anywhere between that. III is up to the introitus. I to II is prior to the introitus.
Q. And when you say "introitus," you're referring to the vaginal opening?
A. That is correct.
Q. Now, you indicate here that -- if we're going under "ASSESSMENT AND PLAN," you say here that -- well, let me strike that.
You also note -- note that she has a mild rectocele -- is that correct? -- on page 13.
A. Yes.

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Q. And then under "ASSESSMENT AND PLAN" on the same page, page 13, you say the rectocele is asymptomatic so you don't feel that you need to treat that at that time; is that correct?
A. Yes.
Q. And so did you -- did you end up treating her for rectocele?
A. No.
Q. And so you did not ever perform a posterior repair on Ms. Smith; is that correct?
A. That is correct.
Q. Now, it says "...but I do think she will be a good candidate for a cystocele repair" --
A. Uh-huh.
Q. -- "and sling placement." Do you see that? And "I have talked to her about the possibility of doing an Avaulta repair as well as a cystoscopy."
A. Uh-huh.
Q. Okay. And that's a "Yes" that you see that?
A. That is a "Yes."
Q. So why did you think Ms. Smith would be a good candidate for a cystocele repair?
A. Because she had a cystocele and she was also having stress incontinence at the same time.
Q. And when you say "a cystocele repair," you're

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referring to a repair with the Avaulta; is that right? that she'd be a good candidate for that.
A. Yes.
Q. Was Ms. Smith's cystocele symptomatic?
A. From my history I'm not mentioning anything. And, again, I don't have a true recollection of this. I'm just going by my medical notes.
Q. Okay. So based off what you -- you can recall now and -- and looking at the records --
A. Uh-huh.
Q. -- you don't have anything to add about that?
A. No.
Q. So what were Ms. Smith's risk factors for development of SUI and cystocele?
A. Mostly having had babies.
Q. And when you say "babies," are you referring to the six pregnancies and six vaginal deliveries she had?
A. Yes.
Q. What effect, if any, could those multiple deliveries have on Ms. Smith's pelvic floor?
A. It can cause incontinence and prolapse.
Q. And was she at risk for future pelvic issues due -- due to the number of pregnancies she had?
A. What do you mean by "future"?

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Q. Just at risk for having pelvic -- you know, additional pelvic issues.
A. After the birth of her children?
Q. Yes. After six pregnancies.
A. Yes.
Q. And vaginal births I meant to say.
Now, how about the previous tubal ligation? the 1999 procedure. What effect, if any, could that have on Ms. Smith's pelvic floor?
A. I want to say none.
Q. Okay. Could it lead to scarring?
A. It could.
Q. What about the a- -- is it ablation? Is that the correct way to pronounce it?
A. Yes.
Q. -- in 2006 could -- could that -- what effect, if any, could that have on Ms. Smith's pelvic floor?
A. And I'm sorry. What kind of ablation did she have? "Ablation" is a very generic term.
Q. I -- I just have what's done -- what's done here in your past surgical history, ablation in 2005. If you don't recall the specifics of it, then that's fine.
A. I don't recall the specifics of it.
Q. And then what about the D&C? Which what does

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that stand for?
A. Dilation and curettage.
Q. And what effect, if any, could that have on Ms. Smith's pelvic floor?
A. Probably nothing.
Q. Okay. Would it -- could it also lead -- lead to scarring?
A. It could.
Q. Okay. Now, it says a full -- we're on page 13 again -- "A full PARQ," P-A-R-Q, "conference was held regarding the procedure." Now, a P-R -- PARQ, P-A-R-Q, conference is required by law here in Oregon; right?
A. That is correct.
Q. And can you describe to us what it is.
A. It's basically the consent form we get for surgery.
Q. Okay. So I -- I know that the acronym stands for something, but I'm just going to sparse [verbatim] it out with you. So at this time you would have discussed the risks, benefits, and options to Ms. Smith; is that correct?
A. That is correct.
Q. That would be part of this conference?
A. Yes.

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Q. Can you tell me what risks you discussed with Ms. Smith about the mesh procedure?
A. So, again, I don't recall the specifics, but my standard consent that I give for all patients who are undergoing mesh -- vaginal mesh procedures include risks from the anesthesia; risks of bleeding; infection; risks of prolapse recurrence; risks of mesh-related risks including extrusion, migration, pain.
Q. Would you have -- would part of your practice be warning about the potential of pelvic and vaginal pain?
A. Yes.
Q. And the potential for a risk of dyspareunia?
A. Yes.
Q. And -- and vaginal scarring?
A. Yes.
Q. And this was -- although you don't have a specific recollection -- sorry. Let me -- let me strike that.
This was part of your common practice, to warn any of your patients in 2008 who were having a mesh procedure; correct?
A. Correct.
Q. Okay. And when you go over risks with a

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patient, you assess whether they have the ability to understand the risks you describe; right?
A. Yes.
Q. And -- and -- and when you went over the risks with Ms. Smith, did you believe she was capable of making an informed consent?
A. I believe she was.
Q. Now, as far as alternatives, it says you discussed options with Ms. Smith. What -- what were those options?
A. Again, I don't recall specifically, but my standard options are pelvic floor exercises including kegel exercises.
Q. Did you discuss medications?
A. Medications are not relevant or appropriate in this case.
Q. Okay. Was she interested in pelvic floor or physical therapy?
A. Not to my knowledge. Again, I don't recall.
Q. Any other alternatives for Ms. Smith that you haven't mentioned already?
A. I don't think so.
Q. Okay. And she elected to proceed with the surgery; is that correct?
A. Yes.

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Q. And, finally, it says here "All questions were answered and the patient agrees to proceed." Do you see that?
A. Yes.
Q. By noting this, you're indicating that Ms. Smith consented to the procedure and you answered any questions she may have had at the time; correct?
A. That is correct.
Q. Can you remember if Ms. Smith had any questions?
A. I do not remember specifically.
Q. Do you know if anyone else was present with her at the time?
A. I don't remember.
Q. Okay. So let's see. If we can go to page 32. It looks like at the bottom here it says -- this is the pre-op report by -- and pre-op history and physical that Dr. Crawford performs on 10/10/2008. Is that --
A. Yes.
Q. Okay. And it indicates on page 34 that you were cc'd here.
A. Yes.
Q. Okay. And so you would have read this record, I presume.

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A. Yes.
Q. And it says on page 34 -- if you go to "GYNECOLOGICAL," the second line, it says "On my exam, there is no evidence of significant cystocele or rectocele, and she appears apically supported. However, on exam by Dr. Kim, she has a mild rectocele and cystocele."
Do you see that?
A. Yes.
Q. Did you and Dr. Crawford talk about this? Were you essentially saying the same thing? I just wanted to reconcile.
A. We did not speci- -- I don't recall specifically talking about it.
Q. Okay. Where -- are you -- are you guys saying the same thing in some sense or -- or you don't know?
A. Well, Dr. Crawford thought there was no significant cystocele or rectocele.
Q. And -- and you don't recall any discussion with Dr. Crawford about it?
A. No.
Q. Okay. If we go to page 32, and it's right above the "PAST OBSTETRIC HISTORY." It says "Ms. Smith will be admitted on January 15, 2008, for a planned...hysterectomy" -- sorry -- "for a planned

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total vaginal hysterectomy with a possible sling procedure and cystocele repair. Depending on her exam, she may also benefit from an Avaulta mesh and/or evaluation with cystoscopy."
Did I read that correctly?
A. Yes.
Q. So -- and then on January 15, 2008, Ms. Smith was, indeed, implanted with the Avaulta mesh to treat her cystocele; right?
A. Yes.
Q. So at the time of the surgery, do you recall talking to Dr. Crawford about putting in the Avaulta, or was that a decision that you made?
A. I'm assuming I talked to her about it. I mean, this is always a joint decision that we make. Although Dr. Crawford usually defers to me as I tend to do more pelvic floor prolapses.
Q. Okay. And do you remember any specifics about whatever discussion you may have had at the time?
A. I do not recall.
Q. And so would you say -- I think you kind of answered this. But the decision to implant the Avaulta was -- was your decision. It wasn't a -- a -- a mutual decision with the two of you?
A. Most likely my decision, yes.

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Q. And so you determined that Ms. Smith was a good candidate for the Avaulta; right?
A. Yes.
Q. And that's -- and it seemed like -- like you were going to make that decision once you actually went in for the surgery; is that -- that correct?
A. Yes.
Q. And so why -- why, when you went into -- actually went in for the surgery did you determine she was a good candidate?
A. Once the patients are under anesthesia and they're relaxed, you can actually see whether there is more of a prolapse or not, especially after the hysterectomy has been performed. Then it's even more evident whether there is going to be issues with prolapse.
Q. And -- and these were the indications for -- for why you ended up implanting the Avaulta; correct?
A. Yes.
Q. Now, it's your understanding that Ms. Smith signed a consent form for -- for her procedure; is that right?
A. Yes.
Q. Okay. So I want to go to the implant procedure record which is on 20 -- page 27. And so,

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first, Ms. Smith had a hysterectomy -- hysterectomy performed by Dr. Crawford, and you assisted in that; correct?
A. Yes, I believe so.
Q. Okay. Were there any complications with that hysterectomy procedure?
A. Not that I recall.
Q. And then you performed the implants of the Align TO and the Avaulta Plus Anterior; correct?
A. Yes.
Q. And Dr. Crawford assisted?
A. That is correct.
Q. Okay. It looks like the Avaulta Plus Anterior was implanted first; is that right?
A. Before the --
Q. Align.
A. Yes.
Q. Can you --
A. After the hysterectomy.
Q. Yes. After the hysterectomy, but before the Align; is that right?
A. Yes.
Q. Can you describe to me your implant technique for the Avaulta Plus Anterior in Ms. Smith?
A. Well, it is described in detail in this

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operative report. Would you like me to read the operative report?
Q. If you're just going to read what's in the operative report, then that's not necessary.
A. Okay.
Q. But if you have anything additional to add to it or -- or just to describe how you do this procedure in general, I'd appreciate it.
A. I mean, it's -- if you want me -- I mean, I don't recall exactly the actual procedure with Ms. Smith, it being 11 years ago or more than that. So I can just tell you in general what I do --
Q. Okay.
A. -- and that this was an uneventful surgery. But the actual specifics of this particular surgery, no, I -- I cannot tell you.
Q. Can you -- can you just describe to me, though, the technique that you use, I guess, for implanting the Avaulta Plus Anterior back in 2008?
A. So I inject with local anesthesia which provides a little bit of hydrodistention. I make an incision in the anterior vaginal wall, dissect with usually Metzenbaum scissors. And -- and then we let the mesh soak for a little while. This one required it to be soaked. And then we pass a needle that goes

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through the transobturator for the very proximal -- I'm sorry -- the very distal arms.
And you have to then -- I believe with the Avaulta you have to do another incision -- I'm sorry. I haven't done the Avaulta in quite some time so -- I guess right in front of the ischial spine. Yes. And then you have to -- there's -- there are four arms on it as you saw in the diagram. The very top arm, or very distal arm, goes through the transobturator space. The very proximal arm goes right in front of the ischial spine I believe is what we were using at the time.
Q. Okay. And, again, you said it was uneventful, so no complications --
A. Correct.
Q. -- with the Avaulta?
And then with the Align, no complications with --
A. Yes.
Q. -- implanting that; correct?
MR. POTTER: Just for --
BY MR. MANDELL:
Q. Sorry. When you say "Yes," you mean no complications; is that correct? Or were there any complications with the Align surgery?

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A. There were no complications I can recall from the surgery.
Q. Okay.
MR. POTTER: What I was going to say is you were starting to talk over --
THE WITNESS: Sorry. Yes. I realized that. And I'm talking over you too.
MR. POTTER: Let him get his questions out --
THE WITNESS: Yes.
MR. POTTER: -- and then answer.
BY MR. MANDELL:
Q. So now, if we go to page 8, this is Ms. Smith's post-op visit. Do you see that?
And you indicate the patient is doing extremely well. Do you see that?
A. Yes.
Q. Okay. And that's -- that's a true statement -- right? -- that you wrote -- that you wrote at the time.
A. Yes.
Q. Okay. And then if we go to -- so it says here on -- sorry. Still on page 8, it says "She is doing extremely well. She is urinating without any problems. She is no longer having any problems with

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stress incontinence, and she is also having regular bowel movements as well."

So it appears at this time her SUI and cystocele are both resolved; is that correct?

A. Yes.

MS. SCARCELLO: Object to form.

BY MR. MANDELL:

Q. Given the procedure was a success; is that correct?

MS. SCARCELLO: Object to form.

THE WITNESS: Yes.

BY MR. MANDELL:

Q. Now, you also note here under where it says "O," the last sentence, it says "There is no sign of any mesh extrusion." And so at this time there was no extrusion; is that correct?

A. Yes.

Q. Okay. And then you asked to see her back in six weeks. Do you see that?

A. Yes.

Q. And do you see any record of Ms. Smith returning in six weeks?

A. It does say on April 3rd that she had rescheduled her appointment.

Q. And then did she ever come in again after

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April 3rd after -- or after that note?

A. Does not look like it until January.

Q. So you hadn't seen Ms. Smith until January 2009 when she comes back to you complaining of feeling -- of her husband feeling mesh at the time of having sex; right?

A. Yes.

Q. Now, you prescribed her estrogen cream. Do -- do you know how long you would have prescribed her to be taking that estrogen cream after this post-op in -- in 2/13/2008?

A. I usually like to prescribe estrogen cream for the first, at least, three months. And then, when I examine them again after three months, if everything looks good, a lot of times I have them stop it.

Q. So you don't know if -- if Ms. Smith continued to use the estrogen cream because she didn't come back within three months; is that correct?

A. That is correct.

Q. And she -- and -- and you were unable to, then, assess if she needed to continue estrogen cream because she never came back; is that right?

MS. SCARCELLO: Object to form.

BY MR. MANDELL:

Q. Until 2009.

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A. That is correct.

Q. Okay. And is it true that estrogen cream can help resolve pain and dyspareunia?

A. It can.

Q. So now if we go to this January 2009 record, it indicates, again, here that she's not having any SUI issues but it appears her complaint is some -- what you assess is mesh erosion at the proximal edge of the mesh; is that right?

A. Yes.

Q. Do you know what device you're referring to here? Was it the Avaulta or the Align?

MS. SCARCELLO: Object to form.

THE WITNESS: This is most likely the Avaulta.

BY MR. MANDELL:

Q. Okay. Now, is there any complaint of pain related to this erosion? If there was, would you have noted that here in the record?

MS. SCARCELLO: Object to form.

THE WITNESS: There's a mention that her husband noticed something during sexual intercourse.

BY MR. MANDELL:

Q. But is there any -- there's no indication that she was feeling any pain; is that correct?

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MS. SCARCELLO: Object to form.

BY MR. MANDELL:

Q. Whether it be -- whether that be pelvic vaginal pain or dyspareunia pain.

A. That is correct.

Q. Okay. And if she would have told you that, you would have noted it here; correct?

MS. SCARCELLO: Object to form.

THE WITNESS: Well, I did note that the patient states up until a month ago she did not feel anything.

BY MR. MANDELL:

Q. Okay. But -- but, again, it's not noting pain. It's feeling something; right?

A. Correct.

Q. Okay. Do you recall her telling you that she felt any pain?

A. I do not recall.

Q. If she had told you that she was having a sharp pain she felt during sex, is that something you would have noted here?

MS. SCARCELLO: Object to form.

THE WITNESS: Most likely.

BY MR. MANDELL:

Q. Now, just to clarify, it says here that

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"She...stopped using the Estrace cream several months ago," and that was the cream you prescribed to her; right?
A. Yes.
Q. And you never told her to stop using that cream; right?
A. No.
Q. Okay. And what effect of not using that cream, what effect could that have on Ms. Smith?
A. It could cause some vaginal irritation.
Q. Okay. Dryness? Discomfort? Does that -- does that sound correct?
A. Yes.
Q. Dyspareunia even?
A. Perhaps.
Q. Now, she claims she started a more rigorous exercise regime. Is that -- could that have been any contribution to this extrusion that occurred?
MS. SCARCELLO: Object to form.
THE WITNESS: She thinks it was.
BY MR. MANDELL:
Q. In your opinion.
A. I -- I -- I can't say.
Q. Okay. Now, you refer to it as erosion here, but in the operating report, you referred to it as an

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extrusion. In your mind, is there any difference?
A. No.
Q. So to clarify, you saw the mesh coming through the vaginal mucosa which is an erosion outside, and that's sometimes referred to as an extrusion; right?
A. That is correct.
Q. Now, it says "A full PARQ conference was held for the procedure, which is a revision and excision of vaginal mesh erosion [and] was discussed at length with the patient. The alternatives, risks, and benefits were also explained and the patient agrees to proceed."
Do you see that?
A. Yes.
Q. Okay. And that -- that would be the same -- would that have been the same conversation that we discussed you had with the implant procedure?
A. Well, it's slightly different because the mesh is already in.
Q. What -- as far -- well, let me restate it.
As far as risks involved, would there have been any additional risks you would have added different from what you told her in the implant PARQ conference?
A. No.

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Q. Okay. So you still would have warned her about the risks of continue -- you know, the risks of dyspareunia; is that correct?
A. Yes.
Q. And the risk of vaginal or pelvic pain; is that correct?
A. Yes.
Q. And the risk of additional scarring; is that correct?
A. Yes.
Q. Okay. Now, it says here you -- I think you recommended to perform surgery, but did you provide Ms. Smith with other options?
A. I usually provide them with continue with estrogen cream to see if that might help it.
Q. And from -- from your recollection in this record, was -- was Ms. Smith interested in that?
A. Again, I don't recall but knowing -- since she scheduled surgery soon afterwards, I suspect not.
Q. Okay. And she elected to proceed with the surgery; right?
A. Yes.
Q. You -- you also indicate -- indicated -- indicated to her one of the risks would be failure of the procedure?

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A. Yes.
Q. Okay. Now, on the operating report on page -- I think it's 24. You say "...a little bit of mesh extruding..." Can you tell me what you mean by "a little bit"?
A. I think I mean a little bit. Again, I -- I -- I, again, don't recall exactly; so I don't have the dimensions for you.
Q. Okay. That's okay. But -- but overall would you say that this was a very minor procedure?
MS. SCARCELLO: Object to form.
THE WITNESS: Yes.
BY MR. MANDELL:
Q. And -- and you would consider this extrusion an expected risk of any pelvic mesh procedure; right?
A. It can happen, yes.
Q. And it was uneventful and no complications; right?
A. From which surgery?
Q. This one. This 2009 surgery was uneventful and no complications; right?
A. Yes.
Q. Did you conclude why this extrusion happened?
A. No.
Q. Would you say that tissue quality or -- or

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failure to use estrogen cream could have been a reason?
A. Potentially.
Q. Just because you needed to revise the mesh, it didn't mean there was anything wrong with the mesh; is that right?
A. That is correct.
Q. Now, let's go to her post-op after this. This is February 2009, page 6. And it looks like here you note she's doing extremely well, putting on cream and not having any problems and no evidence of mesh extrusion at this time; is that correct?
A. Yes.
This is -- I'm sorry -- page?
Q. I have it on page 9.
A. 9?
Q. Or is it 8? I think it's 8. Sorry. This would be -- wait. 6. Page 6?
MR. POTTER: Page 6.
BY MR. MANDELL:
Q. Page 6. I apologize.
A. Okay.
Q. This is page 6. So this is after her revision surgery, and you're noting she's doing very well, not having any problems. Do you see all of that?

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A. Yes.
Q. Okay. And there's no evidence of any mesh extrusion at this time; is that right?
A. That is correct.
Q. Okay. And then on page 5, you have another follow-up with her. And it says she's doing extremely well, no longer feeling any mesh, and that you do not feel any more signs of mesh extrusion. Is that correct?
A. Yes.
Q. At this time she would have been permitted to have sex; correct?
A. This is how many weeks after surgery?
Q. About two months after surgery.
A. Yes.
Q. And if she had any pelvic vaginal pain or dyspareunia, if she had indicated that to you, that's something you would have noted here; right?
A. Yes.
Q. Okay. So now we're on, I believe, her last visit to you which is page 4. And this is April 2009. Do you see that?
A. Yes.
Q. Again, you indicate she's doing extremely well and that the excision surgery was successful. You

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indicate that she's even quite happy with the results; is that right?
A. Yes.
Q. So, in your opinion, was the excision successful?
A. Yes.
Q. If Ms. Smith had indicated she had any pelvic vaginal pain or dyspareunia at this time, that's something you would have noted here; right?
A. Yes.
Q. During your examination, at any point from the revision to these examinations, did you notice any excessive scarring or banding?
MS. SCARCELLO: Object to form.
THE WITNESS: Not that I recall.
BY MR. MANDELL:
Q. And if you would -- if you would have noticed that, is that something you would have noted?
A. Most likely.
Q. Okay. So after reviewing the records, this looks like your last contact with Ms. Smith; is that correct?
A. Yes.
Q. And just to confirm, when a patient comes to you to follow up, do you ask them if they're -- if

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they have any problems?
A. You mean just routinely?
Q. Yes.
A. For any patients?
Q. Yes.
A. Yes.
Q. And -- okay. And then -- and we also went over all of her post-op records, and, again, there's no mention of Ms. Smith's SUI or cystocele after her implant; is that correct? Of symptoms.
A. Right. I mentioned that she's doing well --
Q. Right.
A. -- and no longer leaking.
Q. So after her implant surgery, you would agree that those issues, based on the last time you saw her, were corrected and resolved.
A. Yes.
Q. In other words, the Align and Avaulta did what they were intended to do; correct?
A. Yes.
Q. Ms. -- did Ms. Smith have a good prognosis for her POP and SUI moving forward from the last time you saw her?
A. Yes.
MS. SCARCELLO: Object to form.

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BY MR. MANDELL:
Q. And you never formed an opinion that anything was wrong with the Align or Avaulta that were implanted in Ms. Smith; correct?
MS. SCARCELLO: Object to form.
THE WITNESS: No opinion.
BY MR. MANDELL:
Q. Okay. During the exam and subsequent surgeries you had with Ms. Smith, the only thing you -- you -- that she had was extrusion; is that correct?
A. Correct.
Q. Other than that you didn't note any problems with the mesh; is that correct?
A. Correct.
Q. So based on all the risks and benefits you understood to be related to the Align and Avaulta Plus, is it fair to say that as of January 2008, what you knew at that time, you felt the Align and Avaulta was safe and effective and appropriate to treat Ms. Smith for her stress urinary incontinence and cystocele?
MR. POTTER: Object to form.
Go ahead.
THE WITNESS: This is prior to the surgery?

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BY MR. MANDELL:
Q. Yes.
A. Yes.
Q. And during your care and treatment of Ms. Smith, you never came to the conclusion that there was a specific aspect of the Align or Avaulta that caused any injury to her; correct?
A. Yes.
MS. SCARCELLO: Object to form.
BY MR. MANDELL:
Q. In 2008 you agree that you felt the Align and Avaulta gave Ms. Smith the best chance of success with respect to her stress urinary incontinence and cystocele?
A. Yes.
Q. And you agree -- sorry. I won't say that one.
Now, just real quickly, opposing counsel mentioned that you were a preceptor for Bard. Do you recall her talking to you about that?
A. Yes.
Q. Do you know if Bard ever paid you any money?
A. They may have.
Q. Okay.
A. Although I don't recall.
Q. The -- now, the fact that -- the fact that you

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received training -- I'm sorry. Let me strike that again.
Did you ever feel coerced to use a specific product because you attended a training facilitated by Bard?
A. Did I feel --
MS. SCARCELLO: Object to form.
THE WITNESS: -- coerced?
BY MR. MANDELL:
Q. Yes.
A. No.
Q. And getting -- or what was your -- your experience at the trainings, did you find those to be beneficial to learn about the products?
A. Yes. But I'm going to just say generally because I do not remember.
Q. Okay. And you agree that cadaver training with experienced doctors is a valuable -- is valuable for patient care?
A. Yes.
Q. You don't feel like the training Bard offered is -- is a substitute for a surgeon's general training and experience and own professional responsibility to ensure that they know how to perform the surgeries that they're performing with medical devices such as

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the Align and Avaulta?
MR. POTTER: Object to form.
MS. SCARCELLO: Object to form.
THE WITNESS: So the question you're asking me is, is the cadaver training a substitute for --
BY MR. MANDELL:
Q. For your own training.
A. It is not a substitute.
Q. Okay. Now, you obviously returned -- received training to perform surgeries in medical school and residency; right?
A. Yes.
Q. You also had training regarding surgery for treatment of SUI and POP in medical and residency; correct?
A. Yes.
Q. Medical school and residency.
And the training and teaching work that you had done for Bard, was that done for the good of patients in general?
A. Yes.
Q. You don't feel that the training and teaching had -- had any -- or do you feel that the training and teaching had any influence or bias over with -- over

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you with regard to your views on the appropriateness of the use of a transvaginal mesh, whether it's the Align or Avaulta, back in 2008?
MR. POTTER: Object to form.
MS. SCARCELLO: Join.
MR. POTTER: You're talking teaching and training she received or teaching and training that --
MR. MANDELL: Yeah.
MR. POTTER: -- she was supposedly doing?
MR. MANDELL: So let me rephrase that.
BY MR. MANDELL:
Q. The -- with regard to the teaching and training as it -- as it applies to Bard --
A. That I received.
Q. The teach -- the training that you received and the -- and the -- the preceptor that you -- that you did for Bard, focusing on that.
MR. POTTER: Well, and that's my objection. I don't think we've ever established exactly what she did as a --
MR. MANDELL: Oh.
MR. POTTER: -- preceptor or if she, in fact, did it.
BY MR. MANDELL:
Q. Do you know -- do you know if you ever acted

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as a preceptor for Bard?
MR. POTTER: Object to form. Asked and answered.
THE WITNESS: I believe I did act as a preceptor. Again, I don't recall the numbers.
BY MR. MANDELL:
Q. Gotcha.
So your -- your training with Bard and -- and your -- and being a preceptor for Bard, did that have any influence or bias over you with regards to your views on the appropriateness of using transvaginal mesh such as the Align or Avaulta?
A. No.
Q. Okay. Did it affect your medical -- medical judgment in your decision to implant the Avaulta Plus and Align TO in Ms. Smith?
A. No.
Q. Now, counsel had asked you about training that you did receive with the Avaulta. She referred to it as Avaulta products. Are you able to tell me if those were the Avaulta or Avaulta Plus products?
A. I don't recall.
Q. And she kept using the phrase that the training was one of the ways or only way you could receive in-depth knowledge of the Align or Avaulta

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Plus. Do you recall that type of questioning?
MS. SCARCELLO: Object to the form of the question.
THE WITNESS: I'm not sure she ever said "only way to train."
BY MR. MANDELL:
Q. Or -- or -- or was a way for you to receive in-depth knowledge of those products.
A. I don't know if she said that, but okay.
Q. Let's -- let's -- let's try to ask it a different way.
A. Sure.
Q. Would you agree that those trainings were not the only way for you to know knowledge of products for midurethral slings and transvaginal mesh?
A. Yes.
Q. Okay. Finally, she -- she also brought up an MSDS sheet, a material safety data sheet. She didn't show you the document. Is that something you rely on when making a medical -- medical decision in your practice?
MS. SCARCELLO: Object to form.
THE WITNESS: No.
BY MR. MANDELL:
Q. Okay. You don't -- do you even know what that

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is?
A. No.
MR. MANDELL: Okay. I will reserve whatever time I have remaining. Pass the witness.

REDIRECT EXAMINATION

BY MS. SCARCELLO:
Q. All right. So, Doctor, I have a few follow-up questions regarding specifically your care and treatment of the plaintiff. So if you could turn to page 12 of the medical records. And this is from your November 30, 2007, appointment with Ms. Smith.
And counsel asked you a few questions about the history of present illness noted in the record here. And in the interest in being complete, am I correct that the history of present illness taken down by you says that -- starting in about the middle of the paragraph, "There are days when she does not have to change her pad at all, but there are other days when she changes it about twice, especially if she has a cold"; is that correct?
A. Yes.
Q. Did -- was it your understanding that Ms. Smith's urinary incontinence was having a profound

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impact on her life?
MR. MANDELL: Object to form.
THE WITNESS: I don't know.
BY MS. SCARCELLO:
Q. Was there any indication that -- that this was having a severe impact on her life?
MR. MANDELL: Object to form.
THE WITNESS: I don't know. I'm always assuming that, when a patient comes to see me for a problem, it is affecting their life.
BY MS. SCARCELLO:
Q. Okay. Fair enough. But I guess I'm just asking, there are certainly -- in your practice you've certainly seen pelvic organ prolapse that is much more severe than Ms. Smith's; isn't that correct?
MR. MANDELL: Object to form.
THE WITNESS: I've seen all severity.
BY MS. SCARCELLO:
Q. And is it fair to say that there are other patients who you have treated who have reported the impact on their life as being more substantial than what is noted here with respect to Ms. Smith's -- the impact on her life?
MR. MANDELL: Object to form.
MR. POTTER: Join.

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THE WITNESS: There are patients who complain more, yes.
BY MS. SCARCELLO:
Q. Okay. And is it fair to say that Ms. Smith doesn't seem to be the type of person who complains a lot?
MR. MANDELL: Object to form.
MR. POTTER: Join.
THE WITNESS: I have no idea.
BY MS. SCARCELLO:
Q. Okay. You don't recall?
A. No.
Q. So the next sentence after the one I just read says that "She does not have any issues with urgency or urge incontinence"; is that right?
A. Yes.
Q. Are there other women who have pelvic organ prolapse and incontinence that results in urgency and urge incontinence?
MR. MANDELL: Object to form.
THE WITNESS: Yes.
BY MS. SCARCELLO:
Q. You mention here that she does not have to push or strain to have a bowel movement and that she has not had any problems with urinary tract

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infections; is that right?
A. Yes.
Q. Counsel asked you some questions about Ms. Smith's past surgical history, specifically whether a tubal ligation from 1988 may have potentially resulted in vaginal scarring. Do you recall that line of questioning?
MR. MANDELL: Object to form.
THE WITNESS: Yes.
BY MS. SCARCELLO:
Q. And you indicated -- well, strike that.
Is there any indication in this record that you found scarring in Ms. Smith's pelvic area that -- that you would attribute to the tubal ligation?
MR. MANDELL: Object to form.
THE WITNESS: No.
BY MS. SCARCELLO:
Q. Is there any indication that the D&C performed in 1980 caused scarring?
A. Not that I indicated.
Q. And if -- if Ms. Smith had excessive scarring in her pelvic area, would you have noted that in your notes?
A. Most likely.

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Q. Okay. If you'll turn to the next page, there's discussion -- I specifically want to ask about the pelvic exam. There are a lot of medical words in that -- in those sentences that follow. So could you just read that into the record for us?
A. Which part?
Q. After "PELVIC EXAM." Starting with "PELVIC EXAM" and ending before the skin exam.
A. "Reveals a normal vaginal introitus, normal labia, normal urethral meatus, nontender urethra, and nontender bladder. She does have a grade I to II cystocele and a mild rectocele. I do not feel any cervical motion tenderness. She does not have any real uterine descensus. There is no evidence of inguinal lymphadenopathy. No peripheral edema."
Q. So can you sort of explain in layman terms what those findings mean? what that sentence -- those sentences mean.
A. Line by line? Normal vaginal introitus?
Q. Well, yeah. Right. You don't have to go through every single -- every single thing that is mentioned in your notes, but if you could just in general explain what you found on the pelvic exam.
A. So she has POP, Grade I to II mild rectocele.
Q. And that was the extent of the findings during

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your pelvic exam; is that correct?
A. Correct.
Q. With respect to your assessment and plan, you noted the rectocele is asymptomatic; is that right?
A. Yes.
Q. And so you did not feel that you needed to treat that at that time; is that right?
A. Yes.
Q. But you did state that you think she will be a good candidate for a cystocele repair and sling placement; is that right?
A. Yes.
Q. With respect to the PARQ conference, I think you previously mentioned the -- the risks and benefits that you would have likely gone over with Ms. Smith. With respect to an informed consent form, is that -- is there an informed consent signed before every procedure that you perform?
A. The hospital requires an informed consent form.
Q. Okay. And so if there isn't an informed consent form for the implant procedure that is in these records which was signed by Ms. Smith, then that -- that is possible -- strike that.
If these records don't include an informed

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consent form that was signed by Ms. Smith, does that mean that an informed consent was never signed by her?
MR. MANDELL: Object to form.
MR. POTTER: Object to form.
THE WITNESS: No.
BY MS. SCARCELLO:
Q. Basically what I'm trying to ask is: Is it possible that an informed consent was signed and lost?
MR. POTTER: Object to form.
MR. MANDELL: Object to form.
THE WITNESS: I mean, possibly. Your conjecture is as good as mine.
BY MS. SCARCELLO:
Q. Okay. My concern is -- is there any chance that you moved forward with the implant procedure without having a signed informed consent?
MR. MANDELL: Object to form.
THE WITNESS: Highly unlikely. Again, the hospital -- we cannot go back to the operating room without having an informed consent.
BY MS. SCARCELLO:
Q. Okay. And for the record, we have one that is signed by you. We just don't have one signed by Ms. Smith.
MR. POTTER: Counsel, I'll just put this

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on the record because I was looking at this as well. I don't know whether we've been provided a complete copy of the hospital chart because I also note that, while this was a joint surgery with Dr. Crawford, there's no informed consent form for Dr. Crawford's surgery. So it's possible that whatever you guys have provided to us is not the complete hospital record from that time.
MS. SCARCELLO: Right. It's also possible that what was provided to us and then passed on to you was not complete; so --
MR. POTTER: Right. But what I'm getting at is Dr. Crawford is not in her clinic. So we didn't get Crawford's records. It's possible that whatever you're looking for might somehow be with her records since they did a joint procedure. I'm just putting that out there as a possibility. I don't know that for the record.
MS. SCARCELLO: Okay. I appreciate that.
BY MS. SCARCELLO:
Q. So let's move on to the operative note from the implant procedure if you can turn to page 27. And this was your operative note; is that right?
A. Yes.
Q. And this was dictated by you; is that correct?

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A. Yes.
Q. And it looks like it was dictated on January 15, 2008; is that right?
A. Yes.
Q. So the same day as the procedure.
A. Yes.
Q. And you mentioned previously that there -- there were no complications; is that right?
A. Yes.
Q. You also did a cystourethroscopy to confirm that there was no bladder injury; is that correct?
A. Yes.
Q. I know that I pronounced that incorrectly. I'm sorry.
Why did you opt for using the transobturator sling on Ms. Smith?
A. As opposed to?
Q. As opposed to a retropubic.
A. At the time -- once transobturator slings came into -- came into the market, those I found to be safer, easier, and as effective if not better than retropubic slings.
Q. And is that still your opinion today?
A. Yes.
Q. And do you still perform -- do you still

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perform POP repairs using mesh devices?
A. Well, mesh devices are -- are no longer on the market.
Q. Do you still perform stress urinary -- stress urinary incontinence repairs using transvaginal mesh?
A. Stress incontinence I treat with transobturator tape if that's what you meant.
Q. Did -- did -- did you mention before what product you use -- I'm sorry. We've had multiple depositions today, and I'm -- I'm losing track of who has said what.
Maybe I'll just ask you this: What device do you use for the treatment of -- for the surgical treatment of stress urinary incontinence?
A. I use transobturator tape.
MR. POTTER: What time frame are we talking about?
MS. SCARCELLO: Today.
MR. POTTER: Okay.
BY MS. SCARCELLO:
Q. And what device is that?
A. The one that I'm currently using is the Boston Scientific Obtryx II.
Q. And how long have you been using Boston Scientific Obtryx II?

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A. Very rough time frame, four to five years.
Q. The estimated blood loss was 600 ccs for the entire case. Is that normal for the entire case?
A. Well, I usually don't do hysterectomies, but this counts as the hysterectomy blood loss as well.
Q. Right.
A. Right.
Q. So have you -- I mean, is that something that it would be unexpected to lose 600 ccs in the course of a hysterectomy and the pelvic organ prolapse and stress urinary --
A. It's within --
MR. POTTER: Object to form.
THE WITNESS: -- the normal --
MR. POTTER: Go ahead.
THE WITNESS: -- within the range.
BY MS. SCARCELLO:
Q. Okay. So next, if you'll go to page 9, which is your first follow-up after the event. Again, this was just about a week after the implant; is that right?
A. This is from 1/23/2008?
Q. Yes.
A. Yes.
Q. And you note that "She is doing very well"; is

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that right?
A. Yes.
Q. Do you recall whether those are your words or hers?
A. No.
Q. When you are -- when you're drafting notes of this sort, do you -- do you take down word for word what the patient says?
MR. MANDELL: Object to form.
THE WITNESS: Depends on the situation.
BY MS. SCARCELLO:
Q. In this situation do you think that you did?
A. I don't recall.
Q. And you didn't perform a pelvic exam during this follow-up; is that right?
A. One week after surgery, I do not perform pelvic exams.
Q. Okay. And then the next follow-up is documented on page 8. This is from February 13, 2008. Again, you note that she's here for follow-up from her sling placement about a month ago. She is doing, quote, extremely well.
Again, do you recall Ms. Smith stating in her own words that she's doing extremely well?
MR. MANDELL: Object to form.

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THE WITNESS: I don't recall.
BY MS. SCARCELLO:
Q. You noted that she was no longer having problems with stress incontinence and having regular bowel movements; is that right?
A. Yes.
Q. Did you perform a pelvic exam at this appointment?
A. Yes.
Q. During that pelvic exam, you noticed some Vicryl stitches still in place; is that right?
A. Yes.
Q. Do know that this was normal for four weeks post-op?
A. Yes.
Q. You did note that the cystocele is completely gone; correct?
A. Yes.
Q. You also note that she has good pelvic muscle tone overall; is that right?
A. Yes.
Q. And at this appointment you did not see any sign of mesh extrusion.
A. Yes.
Q. Then last sentence here on this record is "I

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have encouraged her to continue with the estrogen cream for now and...to continue with the pelvic rest"; is that right?
A. Yes.
Q. So then let's go to the January 16, 2009, record which is on page 7. Counsel asked you some questions about reports of pain. Do -- would you have recommended a second procedure if Ms. Smith was not experiencing any pain --
MR. MANDELL: Object to form.
BY MS. SCARCELLO:
Q. -- related to her mesh?
MR. MANDELL: Object to form.
THE WITNESS: Based on the findings of the physical exam? I mean, it's very vague. A second procedure?
BY MS. SCARCELLO:
Q. Would you have -- would you have recommended a revision procedure if Ms. Smith was not experiencing any problems with her mesh?
MR. MANDELL: Object to form.
THE WITNESS: And she had mesh extrusion?
BY MS. SCARCELLO:
Q. Yes.
A. Depends on the significance of her issues and

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whether she was willing to try estrogen cream which is something I always offer as a first-line treatment.
Q. Do women commonly complain of irritation with estrogen cream?
A. It can happen.
MR. MANDELL: Object to form.
THE WITNESS: Yes.
BY MS. SCARCELLO:
Q. And do women commonly discontinue use of estrogen cream if they experience irritation with it?
MR. MANDELL: Object to form.
MR. POTTER: Join.
THE WITNESS: Some do.
BY MS. SCARCELLO:
Q. You noted that on physical exam she had anterior vaginal wall mesh extrusion mostly in the very proximal edge of the mesh; is that right?
A. Yes.
Q. You noted no other abnormalities?
A. Yes.
Q. And so based on that -- well, strike that.
You also note further up on the paper that about a month ago her husband had noticed some evidence of mesh during sexual intercourse; is that right?

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A. Yes.
Q. And that it's becoming progressively worse; is that right?
A. Yes.
Q. Do you know what this means "progressively worse"?
A. Probably he's feeling it more.
Q. Okay. Do you think that, if he is feeling it, that she is feeling it also?
MR. MANDELL: Objection. Calls for speculation.
MR. POTTER: Join.
THE WITNESS: Shall I still answer?
MR. POTTER: If you can.
THE WITNESS: Usually I ask whether they are feeling it or not as well especially if the husband feels it.
BY MS. SCARCELLO:
Q. Okay.
A. The fact that I did not mention it, that she was having pain, to me means that she probably was not having pain at the time. But, again, this is conjecture as well.
Q. Right. Right after that it says "The patient states that up until a month ago, she did not feel

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anything at all"; is that right?
A. Yes.
Q. And so the implication of that is that she's feeling something now. Is that fair?
MR. MANDELL: Object to form. Calls for speculation.
MR. POTTER: Join.
THE WITNESS: Yes.
BY MS. SCARCELLO:
Q. Then you also noted she started a more rigor-- rigorous exercise regime that -- that she thought may have contributed to her current problem; is that right?
A. Yes.
Q. You made a special comment when counsel was asking you about that. You said, "She thought it did." Do you agree with her assumption?
MR. POTTER: Object to form.
Go ahead.
THE WITNESS: That the exercise made things worse?
BY MS. SCARCELLO:
Q. Yes.
A. Do I think as a rule exercise makes pelvic mesh extrusion worse? Is that the question you're

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asking me?
Q. Sure, yeah.
MR. MANDELL: Object to form.
THE WITNESS: No.
BY MS. SCARCELLO:
Q. Okay.
A. Well, depends on the time frame. Because, again, I don't want them to do anything -- this is why I recommend doing pelvic rest for at least three months after surgery.
Q. Right. Okay. But this is in January of 2009 almost exactly one year after the surgery; is that right?
A. Correct.
Q. And she was following up with you during the immediate post-op period when you would have recommended no exercise, no intercourse, and things of that nature; is that right?
MR. MANDELL: Objection.
THE WITNESS: Well, she didn't follow up with me as I wanted to because I -- she only followed up about with me about a month after surgery. I would have recommended no intercourse and no exercise for three months after surgery --
///

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BY MS. SCARCELLO:
Q. Okay.
A. -- as a clarification.
Q. Okay. And would you have made that recommendation to her only if she had come to see you for additional follow-up, or is that something that you would -- that you would tell people routinely?
A. This is pre-op.
MR. MANDELL: Object to form.
BY MS. SCARCELLO:
Q. Okay. So it was at this appointment that you -- you both together decided to move forward with the revision procedure; is that right?
MR. POTTER: Object to form.
Go ahead.
MR. MANDELL: Join.
THE WITNESS: Yes.
BY MS. SCARCELLO:
Q. And you note here under assessment and plan, quote, "...I think this needs to be treated surgically"; is that right?
A. Yes.
Q. So it was your assessment that surgery was indicated; is that correct?
A. Yes.

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Q. And in terms of Ms. Smith's erosion, did you form an opinion as to what was causing -- causing her transvaginal mesh erosion?
MR. MANDELL: Objection. Asked and answered.
THE WITNESS: No.
BY MS. SCARCELLO:
Q. One has to -- could there be any other cause for transvaginal mesh erosion other than the mesh's presence in the pelvic area?
MR. MANDELL: Object to form.
THE WITNESS: You mean are there any other causes -- etiology behind pelvic mesh extrusion?
BY MS. SCARCELLO:
Q. Right.
A. Besides?
Q. Besides the implantation of pelvic mesh.
MR. MANDELL: Object to the form.
THE WITNESS: You mean if there were no mesh implanted, would there be mesh erosion? No.
BY MS. SCARCELLO:
Q. Right. Okay. Thank you.
A. If that's the question.
Q. It -- it was. Thank you.
So based on your finding that the mesh was

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extruding and causing her and her husband some issues, you determined in your medical judgment that it was reasonable to undertake surgical attempts to remove those parts of the mesh that you felt were contributing to the pain?
MR. MANDELL: Object to the form. Misstates facts.
BY MS. SCARCELLO:
Q. Or contributing to the issues. I'm sorry.
MR. MANDELL: Same objections.
MR. POTTER: Join.
THE WITNESS: Yes, I was going to remove the part that had eroded.
BY MS. SCARCELLO:
Q. Okay. And let's look at the op note for the excision which is from January 20, 2009, on page 24.
What was your preoperative diagnosis?
A. Vaginal extrusion.
Q. What was your post-operative diagnosis?
A. Same.
Q. And you performed an excision of the mesh extrusion; is that correct?
A. Yes.
MR. MANDELL: Objection. Asked and answered.

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BY MS. SCARCELLO:
Q. And what were the indications for that procedure?
A. Vaginal mesh extrusion.
Q. And it says here that she recently noticed mesh extruding; and so that's why you all decided to go forward with this revision. Is that right?
MR. MANDELL: Object to form.
THE WITNESS: Yes.
BY MS. SCARCELLO:
Q. The estimated blood loss it says was minimal; is -- is that right?
A. Yes.
Q. And complications listed are none?
A. Yes.
Q. Can you explain for me just generally what you did during the revision procedure?
A. I injected the area around the mesh with local anesthesia. I make an incision usually surrounding the mesh and undermine the mucosa surrounding it. I excised a piece of mesh that was poking out and then make sure I can close everything up without tension.
Q. And you note here that the excess mesh material was removed quite easily?
A. Yes.

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Q. And that the edge of the vaginal incision was, then, undermined which you just described to allow the edges to come back together; is that right?
A. Yes.
Q. And all of the excess mesh material was easily removed?
A. Yes.
Q. And then you used the Vicryl stitches to close the area; is that right?
A. Yes.
Q. So there no complications, no adverse events during the revision procedure.
A. Correct.
Q. And then there was a follow-up on February 6, 2009 on page 6. Again, the words "She is doing extremely well" appear in this record, and I'm wondering if you recall today hearing Ms. Smith say those words to you in her office -- in your office.
MR. MANDELL: Object to form.
THE WITNESS: I do not recall.
BY MS. SCARCELLO:
Q. It says here that she's been using the Estrace cream every day and not having any problems; is that right?
A. Yes.

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Q. You noted that the anterior vaginal wall was healing nicely; is that correct?
A. Yes.
Q. And you also note that you still feel the stitches in place, but there was no evidence of any mesh extrusion; is that correct?
A. Yes.
Q. You also asked her back for a follow-up in four weeks, and she did follow up with you; is that right?
A. Yes.
Q. And that was on March 5, 2009; correct? And those records are on page 5.
A. Yes.
Q. Again, the words "She is doing extremely well" appear in this record. Do you recall Ms. Smith saying that to you in your office on March 5, 2009?
A. No.
Q. Again, you note that she's been putting the cream on every day. Does that mean the Estrace cream?
A. Yes.
Q. Meaning that she wasn't having problems with it; correct?
A. Yes.
Q. Did you do a -- did you do a pelvic exam at

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this appointment?
A. I did.
Q. And you noted that the anterior vaginal wall had healed; is that correct?
A. Yes.
Q. And no more signs of mesh extrusion; correct?
A. Yes.
Q. And then the last time that you saw Ms. Smith was on April 16, 2009, and that record is on page 4. You note that the -- you note that she was seeing you "...status post a mesh excision in January 2009 after an Avaulta surgery, which was really successful and she is here for a follow-up."
Do you recall Ms. Smith saying to you in your office in April 2009 that -- that she believed the Avaulta surgery had gone really well?
MR. MANDELL: Object to form.
THE WITNESS: I do not recall.
BY MS. SCARCELLO:
Q. Again, the words "She is doing extremely well." Do you recall in April of 2009 Ms. Smith saying to you that she felt that she was doing extremely well?
MR. MANDELL: Object to form.
THE WITNESS: I do not recall.

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BY MS. SCARCELLO:
Q. And here she -- you note that she is putting Estrace cream on every day; is that right?
A. Yes.
Q. And it -- it did seem to be causing a little bit of irritation; is that right?
A. Yes.
Q. And we sort of discussed that that -- that irritation can be one possible side effect of the estrogen cream; correct?
MR. MANDELL: Object to form.
THE WITNESS: It can be.
BY MS. SCARCELLO:
Q. Okay. Looks like you also gave her some samples of Vagifem tablets; is that correct?
A. Yes.
Q. That's an alternative to the Estrace cream?
A. Yes.
Q. Okay. If you -- if you would, please look back at the -- the package inserts that counsel provided to you earlier for the Align TO and the Avaulta plus. Specifically with respect to the Align TO, I'm interested in the adverse events, and then with the Avaulta Plus I'm interested in having a conversation about the adverse reactions listed there.

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Do you see any mention in these documents of any problem with persistent delayed healing?
A. No. But I haven't gone through the whole document word by word.
Q. Right. There was a relatively detailed discussion of the adverse reactions with counsel. And, in fact, I believe he read them word for word. So I was just asking, in general, as you look at these documents, do you see any indication that a potential adverse reaction would be persistent delayed healing?
MR. MANDELL: Object to form.
MR. POTTER: Join.
THE WITNESS: Not that I can see.
BY MS. SCARCELLO:
Q. Okay. Do you see anything here about polypropylene mesh degradation?
A. No.
Q. Do you see anything here about excessive mesh contraction in vivo causing the surrounding tissue to shrink or contract?
MR. MANDELL: Object to form.
THE WITNESS: No.
BY MS. SCARCELLO:
Q. Do you see anything in these documents about the products' arms stressing, moving, shrinking, or

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folding?
A. No.
Q. Do you see anything in these documents about the tensile strength, elasticity, and density at the tissue mesh interface causing a mechanical mismatch?
MR. MANDELL: Object to form.
THE WITNESS: No.
BY MS. SCARCELLO:
Q. Do you see any indication in either of these documents that -- or specifically in the Avaulta package insert that the mesh's characteristics were not compatible with the normal -- the natural motion of the female pelvis?
MR. MANDELL: Object to form.
MR. POTTER: Join.
THE WITNESS: No.
MR. POTTER: Just out of curiosity, are you going to run through your whole list of hypothetical questions that you asked her? because I'll be asking for a standing objection again.
MR. MANDELL: Counsel, where are we on time?
MS. SCARCELLO: Let's go off the record.
THE VIDEOGRAPHER: We are off the record at 4:35.

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(Discussion was held off the record.)
THE VIDEOGRAPHER: And we are back on the record at 4:38.
BY MS. SCARCELLO:
Q. So, Dr. Kim, before we went off the record, we were sort of looking at package inserts for the devices that were implanted in Ms. Smith and discussing some side effects that weren't listed.
MR. MANDELL: Object to form.
MS. SCARCELLO: It wasn't a question.
MR. MANDELL: Object to your narrative.
MS. SCARCELLO: I was making a record of what has gone on in the meantime and just reestablishing what's going on because we asked for a time check out of the middle of nowhere. So that's what was happening.
BY MS. SCARCELLO:
Q. With respect to those two package inserts, would you please resume looking at the pages that list the adverse reactions.
With respect to either of these devices, is there any mention of mesh shrinkage or contraction so as to become folded over or twisted in vivo?
MR. MANDELL: Object to form.
MR. POTTER: Object to form. Both

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Exhibits 4 and 5 speak for themselves as to what is and is not in there. And I'd like a standing objection for all of these questions that you're going to ask Dr. Kim as to what's not in these documents so I can quit interrupting.

MR. MANDELL: And I would like to join in that standing objection.

BY MS. SCARCELLO:

Q. Is there any mention in the adverse reaction or adverse event parts of these IFUs regarding mesh inelasticity and stiffness?

A. No.

Q. In general, would you say that Ms. Smith was a compliant patient?

MR. MANDELL: Object to form.

THE WITNESS: She did fail to follow up.

BY MS. SCARCELLO:

Q. So is that a no?

A. I'm just saying she failed to follow up so -- as a post-op patient during the first surgery -- after the first surgery.

Q. She did eventually follow up, though, didn't she?

MR. MANDELL: Object to form.

THE WITNESS: A year later when she had

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problems, but she did not follow up completely after the first surgery.

BY MS. SCARCELLO:

Q. Did she use the estrogen cream that you had prescribed to her?

A. I don't know.

MR. MANDELL: Object to form. Which time are you talking about?

MS. SCARCELLO: Never mind. The records speak for themselves.

BY MS. SCARCELLO:

Q. Do you have -- strike that.

We previously discussed the polypropylene that is used in the transvaginal mesh devices. And you mentioned that you relied on the FDA approval of the devices. Do you recall that?

MR. MANDELL: Object to form.

THE WITNESS: Yes.

BY MS. SCARCELLO:

Q. So is it fair to say that you rely on -- in part, on the FDA clearance process to determine whether a product is safe for implantation?

A. Yes.

Q. And is it your understanding that transvaginal mesh for the treatment of pelvic organ prolapse has

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been recently removed from the market by the FDA?

MR. MANDELL: Object to form.

THE WITNESS: Transvaginal mesh kits have been removed.

BY MS. SCARCELLO:

Q. Right. For the treatment of POP; correct?

A. Yes.

MR. MANDELL: Same objection.

BY MS. SCARCELLO:

Q. And with respect to counsel's questions about the polypropylene mesh's safety, do you have any background in chemical engineering?

MR. MANDELL: Object to form. Never asked about that.

THE WITNESS: No.

BY MS. SCARCELLO:

Q. Do you have any background in materials engineering?

A. No.

Q. Do you have any background in the creation of an implanted device?

A. No.

MR. MANDELL: Object to form.

BY MS. SCARCELLO:

Q. And then regarding the informed consent, the

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surgical consent that you provide isn't presented to the patient to sign -- strike that.

The surgical consent that you provide does not advise the patient whether there is or could be a defect in any medical product or device you were using in the surgery; is that right?

MR. MANDELL: Object to form.

MR. POTTER: Object to form.

THE WITNESS: No.

BY MS. SCARCELLO:

Q. So when you say "No," you mean that potential defects are not addressed in the informed consent?

MR. MANDELL: Object to form.

MR. POTTER: Object to form.

THE WITNESS: No.

BY MS. SCARCELLO:

Q. I'm sorry. I don't understand the "No."

A. No, I don't talk about potential product defects.

Q. Understood.

In the informed consent documents that your patient signed, is there any mention whatsoever of -- of possible risk of a defect -- defective product being used in a procedure?

MR. MANDELL: Object to form.

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MR. POTTER: Object to form.
THE WITNESS: I'm sorry. Repeat the question again. In my informed consent --
BY MS. SCARCELLO:
Q. Right. Is there any mention of a possible risk of a defective product being used in the procedure?
A. No.
MR. POTTER: Form.
BY MS. SCARCELLO:
Q. Is that a part of your risk conversation that you have with patients in the office?
MR. MANDELL: Same objection.
THE WITNESS: Depends on the product.
BY MS. SCARCELLO:
Q. Is that a conversation that you had with Ms. Smith in 2008 about the Avaulta product?
MR. MANDELL: Object to form.
THE WITNESS: No.
BY MS. SCARCELLO:
Q. Is that a conversation that you had with Ms. Smith about the Align TO product?
A. No.
MR. MANDELL: Same objection.
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BY MS. SCARCELLO:
Q. You would never knowingly put a medical device into a patient where you have even the slightest hint of a defect in that device; is that right?
MR. MANDELL: Object to form.
MR. POTTER: Object to form.
Instruct you not to answer.
BY MS. SCARCELLO:
Q. Procedurally, if your patients won't sign informed consents, they can't get a procedure, can they?
MR. POTTER: Object to form.
THE WITNESS: No.
BY MS. SCARCELLO:
Q. And did you trust the manufacturer to provide you with a nondefective medical device at the time that you implanted the Avaulta and Align TO in Ms. Smith?
MR. MANDELL: Object to form.
MR. POTTER: Join.
THE WITNESS: Did I trust them not to give me a defective product?
BY MS. SCARCELLO:
Q. Did you rely on them not to give you a defective product?

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MR. MANDELL: Same objection.
THE WITNESS: Yes.
MS. SCARCELLO: Okay. I have nothing further.

RECROSS-EXAMINATION

BY MR. MANDELL:
Q. Okay. All right. Dr. Kim, there was some discussion of whether we've been able to locate a informed consent for the 2008 surgery of Ms. Smith. Regardless of whether we find the signed informed consent or not, she gave you an informed consent during your PARQ meeting that you had with her prior to the 2008 implant; correct?
A. That is correct.
Q. And you went through all the risks we discussed with her at that time; is that right?
A. Yes.
Q. Now, counsel indicated that -- asked you a bunch of questions of whether certain things were in this IFU for the Avaulta. Do you recall that?
A. Yes.
Q. And we already discussed you did not rely on this document whatsoever in prescribing the Avaulta to

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Ms. Smith; correct?
MS. SCARCELLO: Object to form.
THE WITNESS: Yes.
BY MR. MANDELL:
Q. Okay. And, in fact, she asked you about contraction. And doesn't it say right here under "ADVERSE REACTIONS" that scarification and contraction is an adverse reaction?
A. Yes.
Q. Okay. And knowing that you don't rely on -- on these IFUs, is it fair to say you're -- you're not in any position to say what should or shouldn't be inside the instruction for use?
A. No.
Q. Is that fair? So you would agree with me?
A. I am not in a position to write any IFUs.
Q. Okay. Now, there was some discussion of -- of all of these post-op encounters with Ms. Smith, you know, referring to April 2009 where you say she's doing extremely well; March 2009, extremely well; and February 2009 that she's doing extremely well. Do you recall all that?
MS. SCARCELLO: Object to form.
BY MR. MANDELL:
Q. Is that a "Yes"?

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A. Yes.
Q. Now, counsel said you -- asked you whether Ms. Smith directly said that or not. Do you recall her asking you that?
A. I do recall.
Q. Regardless of whether Ms. Smith told you that or you examined it yourself, the truth is she was doing extremely well; is that -- is that correct?
MS. SCARCELLO: Object to form.
THE WITNESS: If that's what's written on my note, then yes.
BY MR. MANDELL:
Q. Okay. So whatever is written here is the -- is the truth of what you observed at that time; is that correct?
MS. SCARCELLO: Object to form.
THE WITNESS: Yes.
MS. SCARCELLO: Okay.
BY MR. MANDELL:
Q. And so, when you say she was doing extremely well, we can all interpret that to mean she's doing extremely well; is that correct?
MS. SCARCELLO: Object to form.
THE WITNESS: Yes.
///

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BY MR. MANDELL:
Q. Okay. Now, as far as the revision procedure, there was mention of her husband feeling mesh. And then I guess it says -- I apologize here. I guess it says here that -- that up until a month ago she did not feel anything at all. Do you recall that?
A. Yes.
Q. Now, the word "feel" doesn't mean pain; is that correct?
A. No.
Q. Okay. No -- no, I'm incorrect?
A. It does not mean pain.
Q. Okay. So, again, if she had been reporting pain, that would have been something you would have noted here; right?
A. I would have.
Q. Okay. There was a discussion about how women commonly -- or sorry. Let me strike that.
There was a discussion about how estrogen cream may cause irritation. Do you recall counsel discussing that with you?
A. Yes.
Q. After the 2008 implant, is there anything in your notes to indicate that Ms. Smith before she saw you in 2009 was having any type of irritation with the

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estrogen cream?
A. No. Besides that one that I mentioned.
Q. Right. And that was actually in 2009; so --
A. Yes.
Q. -- we're talking about focusing between the implant procedure and your follow-up appointments with her. Was there anything to indicate she was irritated by the estrogen cream?
A. No.
Q. And, again, you never advised her to stop continuing to take that estrogen cream after the 2008 implant procedure; is that correct?
A. That is correct.
MR. MANDELL: Let me just go off the record for one second. I'm sorry.
THE VIDEOGRAPHER: We're off the record at 4:51.
(Pause in the proceeding.)
THE VIDEOGRAPHER: We are back on the record at 4:52.
BY MR. MANDELL:
Q. There -- way -- if you can remember way back at the beginning of this deposition, opposing counsel was asking you about preceptor notes and asking you a bunch of questions about those documents without

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showing them to you. Do you recall that?
MS. SCARCELLO: Object to form.
THE WITNESS: Yes.
BY MR. MANDELL:
Q. All right. So you didn't see those documents today; is that right?
A. That is correct.
Q. And so you don't know whether what she asked you about is accurate or not; is that correct?
A. That's correct.
Q. Okay. So your answers to her questions about that were basically speculation since you don't know what -- what those documents said; is that correct?
MS. SCARCELLO: Object to form.
THE WITNESS: Yes.
BY MR. MANDELL:
Q. I just want to just briefly ask you a couple of questions about training. As a doctor who does surgery on patients for pelvic care, did you find the Bard trainings helpful?
A. Yes.
Q. Do you have any criticisms about those trainings?
A. No.
Q. At these trainings did several other doctors

attend it as well?
A. I believe so. Again, my recollection is poor.
Q. Okay. The fact that you may have been reimbursed for any airfare or travel expenses when taking these trainings, that -- that did not have any effect on your decision to use Bard or feel beholden to Bard; is that correct?
A. No.
Q. So, no, you didn't feel that you -- that you --
A. I was not beholden to Bard.
Q. Thank you.
And you wouldn't rely solely on what a company representative told you with regard to technique, risks, or benefits related to a specific medical device including the Align or Avaulta Plus; correct?
MS. SCARCELLO: Objection.
THE WITNESS: Correct.
MS. SCARCELLO: Asked and answered.
BY MR. MANDELL:
Q. In fact, you don't have any recollection of -- or, in fact, you didn't rely on any statements from Bard in deciding to prescribe the Avaulta Plus and Align TO in Ms. Smith.

MS. SCARCELLO: Objection.
MR. POTTER: Object to form.
MS. SCARCELLO: Form.
THE WITNESS: No.
BY MR. MANDELL:
Q. You didn't -- no, you didn't rely on any statements?
A. Correct.
MR. MANDELL: That is all my questions, and we can go off the record now.
THE VIDEOGRAPHER: We are off the record at 4:54, and this concludes the deposition.
THE COURT REPORTER: Same orders as before.
MS. SCARCELLO: I'm sorry?
THE COURT REPORTER: Same orders as before?
MS. SCARCELLO: Yes, thank you.
MR. MANDELL: Yes.
MR. POTTER: Same issue with the read and sign on the transcript.

(The deposition concluded at 4:54 PM.)

C E R T I F I C A T E

STATE OF OREGON)
) ss.
County of Multnomah)

I, Shellene L. Iverson, a Certified Shorthand Reporter for the State of Oregon, do hereby certify that JIN-HEE KIM, MD, appeared before me and was sworn at said time and place set forth in the caption hereof.

At said time and place I reported in stenotype all testimony adduced and other oral proceedings had in the foregoing matter; that thereafter my notes were reduced into the typewritten transcript; and the foregoing transcript, pages 4 through 175, both inclusive, is a true and correct transcript of my original stenographic notes.

I also certify I am not a relative or employee of any attorney/counsel employed by the parties hereto or financially interested in the action.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal at Portland, Oregon, this 26th day of June 2019.

Shellene L. Iverson
Certified Shorthand Reporter
Certificate No. 03-0386
Certificate Expires: 9/30/21

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

JIN-HEE KIM, M.D. DATE

Subscribed and sworn to before me on this _____day of_____,20___, by _____ _____, proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature _____

EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C. R. BARD, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MDL No. 2187
THIS DOCUMENT RELATES TO:	
BECKY R. SMITH, Plaintiff, vs. C. R. BARD, INC., Defendant.	Case No. 2:15-cv-16402

DEPOSITION OF BECKY R. SMITH
Volume 2, Pages 84-201
Taken on behalf of the Defendant
June 12, 2019
* * *

BE IT REMEMBERED THAT, pursuant to Oregon Rules of Civil Procedure, the deposition of BECKY R. SMITH was taken before Joyce B. Imrie, OCSR No. 94-0293, WCSR No. 2792, on Wednesday, June 12, 2019, commencing at the hour of 1:27 p.m., the proceedings being reported at the Marriott Residence Inn, 10555 NE Tanasbourne Drive, Hillsboro, Oregon.

* * *

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Appearing for Defendant

Also present: Donald Mackie

* * *

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Requested information: NONE

Instruction not to answer: Pages 94, 104, 110, 119, 151, 191, 194

* * *

BECKY R. SMITH,

having first been sworn, testified further under oath as follows:

FURTHER EXAMINATION

BY MR. MANDELL:

Q. Good morning, Ms. Smith. I introduced myself off the record a moment ago, but for the record, my name is Michael Mandell, and I represent C. R. Bard, and I'm here to take your deposition today.

This is your second time being deposed; is that correct?

A. That's correct.

Q. The first time was back in April 2017 for the same case; is that correct?

A. Yes, it is.

Q. Are you taking any drugs or medications that would affect your ability to testify fully and accurately here today?

A. No, I'm not.

Q. So is there any other reason that would affect your ability to testify fully and accurately here today?

A. No.

Q. Now, I know you've had your deposition taken before, but I'm going to go over some of the ground rules

real quick.

Make sure to answer questions verbally. No head or -- shaking of your head or nodding of your head so that the court reporter can get your answers.

Do you understand that?

A. Yes, I do.

Q. We'll try our best not to talk over each other even if you think you know what I'm going to say.

Is that okay?

A. Yes, it is.

Q. If at any time you do not understand my question, please let me know so I can rephrase it. I'm going to assume if you answer my question you understood it.

Is that fair?

A. Yes. That's fair.

Q. If you need a break, let me know. The only thing I ask is, if I have a question, that you finish the answer, and then we will take a break.

Okay?

A. Okay.

Q. You've taken an oath that requires you to tell the truth, the whole truth and nothing but the truth.

Do you understand that?

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A. Yes, I do.
Q. And that is the same oath you would take if you were to testify in court.
Do you understand that?
A. Yes, I do.
Q. Any questions about these instructions?
A. Nope. Not at this time.
Q. Ms. Smith, we're here today because you sued my client, C. R. Bard.
Do you understand that?
A. Yes.
Q. Now, you've already taken a deposition in April 2017, so the purpose of this deposition is to understand all the facts surrounding your suit against Bard that have occurred or changed since your last deposition in 2017.
Okay?
A. Uh-huh.
Q. Now, your suit against Bard specifically pertains to the products called Align TO and the Avaulta Plus Anterior.
Do you understand that?
A. Yes.
Q. You understand that those products were implanted into you January 15, 2008; is that correct?

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A. Yes.
Q. Have you been told by anyone other than your attorneys which product, whether it be the Align or the Avaulta, that has caused your injuries?
A. Nope.
Q. Throughout the deposition I'll be referring to those products as the Align and Avaulta or collectively as the mesh.
Do you understand that?
A. Yes.
Q. I may also use the term "physician," "doctor" or "healthcare provider." I mean those to mean any healthcare provider you saw, whether it be a nurse or doctor.
Do you understand that?
A. Yes.
Q. Also, when I use the term "explant," I'm referring to your November 16, 2018, surgery with Dr. Denman where mesh was removed.
Do you understand that?
A. Yes.
Q. And finally, when I refer to implant, I'm referring to your January 15, 2008, surgery with Dr. Kim.
Do you understand that?
A. Yes.

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Q. Can you drive?
A. Yes.
Q. Did you drive today?
A. Yes.
Q. Do you have a handicapped or disabled person parking sticker on your vehicle?
A. No.
Q. What are your current social activities?
A. I -- let's see. What do I do? I work at a coffee shop a couple days a week. I have dinner with friends at my house or other places. I have grandchildren that come over to my house or I go to theirs.
And children that we spend time together. We do -- we go to grandchildren's events, T-ball, baseball, things like that. We go camping.
Q. Anything else?
A. Off the top of my head, that's what I can think of.
Q. Any new -- any of those new activities since your last deposition in April 2017?
A. No.
Q. Do you currently exercise?
A. I do not.
Q. Are you a member of a gym currently?
A. No, I'm not.

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Q. What did you do to prepare for your deposition today?
A. I got the day off work.
Q. Did you meet with your attorney?
A. Before we came in here. Yes.
Q. Did you have any phone calls with your attorney before that?
A. No.
Q. You said you met with your attorney today before you came in here. How long was that for?
A. I don't know. Ten, 15 minutes.
Q. That's your only meeting with your attorney in relation to today's deposition; is that correct?
A. I just met her. Yes.
Q. For your injuries related to this litigation, has anyone besides a doctor referred you to a treating physician?
A. Can you tell me what you mean by that?
Q. Yeah. Has anyone other than a doctor referred you to any of the doctors that you've seen for treatment?
A. I'm going to say no.
Q. Has anyone other than a doctor recommended you receive any type of medical treatment?
A. No.

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Q. Have your attorneys ever referred you to any doctors?
A. No.
Q. Did you review any documents in preparation for this deposition?
A. No.
Q. Have you ever looked at your medical records with respect to the issues surrounding this case?
A. I have not.
Q. Have you done any Internet research to prepare for today's deposition?
A. No.
Q. Any reading about Bard's products?
A. No.
Q. Any reading about mesh in general?
A. No.
Q. Did you prepare any notes for your deposition here today?
A. I did not.
Q. Have you ever gone to Bard's website?
A. I didn't know that they had a website.
Q. Did you ever speak with anyone at Bard before you had your implant in 2008?
MS. SCARCELLO: I'll object to that question and direct her not to answer. That could have been

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covered in the previous deposition.
(Instruction not to answer.)
Q. BY MR. MANDELL: Have you spoken with anyone at Bard since your last deposition?
A. No, I have not.
Q. Have you ever spoke -- strike that.
Prior to this litigation, had you ever heard of C. R. Bard?
A. No.
Q. Prior to your implant, had you ever heard of C. R. Bard?
MS. SCARCELLO: I'll object to the question and direct her not to answer. It could have been covered in her last one.
(Instruction not to answer.)
Q. BY MR. MANDELL: I'm going to hand you a -- as Exhibit 1, this is the plaintiff fact sheet.
(Marked Deposition Exhibit No. 1.)
Q. BY MR. MANDELL: Have you seen this document before?
A. This is the document I filled out. It looks like the document I filled out.
Q. If you flip back to the last page, is that your signature there?
A. Yes, it is.
Q. That's dated February 8, 2019, correct?

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A. Yes, it is.
Q. You're swearing under penalty of perjury that everything to the best of your knowledge was true and accurate at that time, correct?
A. Yes.
Q. And you reviewed this document before signing it, right?
A. Yes.
Q. Did anyone help you fill out this document?
A. No. I wish they would have. It was hard.
Q. When was the last time you took a look at this?
A. Maybe at my first deposition. I don't know. I haven't seen this in a really long time.
Q. The reason I'm asking is it's dated after your first deposition.
A. That's true. It is. So I must have. Can I just look at it really quickly?
Q. Yes. I was going to actually suggest we could go off the record and give you a moment to look, and let me know if there's anything you want to add or change since it's been a couple months.
A. Yes. Thank you.
MR. MANDELL: So we'll go off the record.
MS. SCARCELLO: That's fine.
(Recess.)

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Q. BY MR. MANDELL: Ms. Smith, we just came back from a brief break so you could review this Exhibit 1 plaintiff fact sheet. I just asked you if there's anything you see in there that you'd like to update or change?
A. There is nothing that I can see. I know -- I realize that I said at first that I hadn't seen this for a really long time, but there is additional information that I put on here, so I did recently send information to my lawyer.
Q. Now, when you say "send information," did you fill out a handwritten one of these plaintiff fact sheets that you sent to your lawyer?
A. Uh-huh.
MS. SCARCELLO: Is that a "yes"?
A. Yes. Sorry.
Q. BY MR. MANDELL: Do you have a copy of that handwritten version?
A. No.
Do I?
No.
Q. It says here on I believe it's page 11, and if you are going by the Bates label, which is on the bottom right-hand corner, it ends with 109, to list any doctors.

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I'm just curious if there's any -- since you filled this out in February 2019, if there's any additional doctors here that aren't listed that you've seen?
A. Dr. Denman is not on here. There she is up at the top. I got that. Okay. So she's the last one. Nikki is in here? So my -- Adrienne Fisher. That's the one.
So I also have Nikki Kuehl who is not on here. She's my primary PA. So she's the one I see. She's the one who referred me to Dr. Waugh, W-A-U-G-H.
Q. And you'll see No. 6 here on this page asks for any additional surgeries or procedures that have occurred.
Has there been anything after this November 16, 2018, surgery that you need to update?
A. No.
Q. You can put that to the side.
Actually, let me take that back. You are currently retired; is that correct?
A. Yes.
Q. That's occurred as of June 30, 2017, correct?
A. Yes.
Q. If you go to page 8 of this plaintiff fact sheet, Exhibit 1, again, Bates No. 106, it says in the

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bottom right-hand corner you are not making a claim for lost wages or lost earning capacity.
Is that true?
A. That's true.
Q. You are still married to Donald Mackie; is that correct?
A. Yes.
Q. He still lives in your home?
A. Yes.
Q. Since April of 2017, have you gone to any marital counseling?
A. Yes.
Q. When did you go to marital counseling?
A. I don't know the dates. I don't know the dates. Sorry.
Q. Do you know who you went to see?
A. Uh-huh. Amy Pulitzer in Manzanita.
Q. Can you spell that for the court reporter?
A. Pulitzer, P-U-L-I-T-Z-E-R.
Q. How many times did you see Dr. Pulitzer?
A. Don and I saw her together and separately, so I'm going to guess four to six times.
Q. When was the last time that you saw her?
A. I don't know the dates. I'm sorry. It hasn't been in the last year. I know that.

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Q. Where is Dr. Pulitzer located again?
A. Manzanita, Oregon.
Q. Since April 2017 have you and Donald Mackie been separated?
A. No.
Q. Has he accompanied you to any doctor visits that occurred after your deposition in April 2017?
A. No.
Q. How about your children? Have they accompanied you to any doctor visits since your deposition in 2017?
A. No.
Q. Have any of your children moved into your home since April '17?
A. No.
Q. Has anyone else accompanied you to any doctor visits since April 2017?
A. Yes. My sister.
Q. Your sister's name?
A. Debbie Smith.
Q. Does Debbie live around here?
A. She lives in Wheeler, Oregon.
Q. Since April 2017 has anyone cared for you after any of your surgeries that you've had? Just to specify, when I say "care," I mean family member or friends?
A. My husband and my sister Deb, I guess, the two of

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them.
Q. Since your last deposition, have you become aware of any family members or friends that have prolapse or incontinence?
A. Can you repeat that question?
MR. MANDELL: Do you want to read it back?
(The reporter read the last question.)
A. No friends, no family.
Q. BY MR. MANDELL: Since your last deposition, have you become aware of any family or friends who have mesh implanted in them?
A. No. There is somebody that I know of that's not a friend or family. She's a local in our community. I guess that's what I want to say. She's not a friend or family.
Q. Have you spoken to her at all?
A. I have spoken to her.
Q. When was -- around what time did you speak to her?
A. It was around the time of my implant or my extraction in 2017 -- no -- '18. Sorry.
Q. What was this person's name?
A. Do I have to give it to you?
Q. Yes.
MS. SCARCELLO: Yes. You have to answer.
A. I feel really bad because she's a very private

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person. It's Sue Crist, C-R-I-S-T.
Q. BY MR. MANDELL: Where does Ms. Crist live?
A. Nehalem.
Q. Did Ms. Crist have a repair involving mesh?
A. I assume she did.
Q. Do you know what product she may have had?
A. No. I have no idea.
Q. Do you know if she filed a lawsuit related to mesh?
A. I know she did not.
Q. What was your discussions that you had with Ms. Crist around 2018?
A. She wanted to know if I knew of a doctor.
Q. A doctor for what?
A. For her mesh. She was having serious problems with her mesh. My sister had talked to someone they had known that I had pain, so she called me and asked about my doctor, who I was seeing.
Then she told me that her doctor had suggested she go to my doctor. She said, you know, I went to her once. She wouldn't take my mesh out. She wouldn't do anything. So I don't want to see her.
I said, well, I really like her. I think she's really great. So that was our conversation.
Q. When you say the doctor, we're referring to Dr. Denman?

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A. Yes. Dr. Denman.
MR. MANDELL: Next I'll introduce as Exhibit 2 the amended notice of deposition for your deposition today. This was served on June 4. There you go.
(Marked Deposition Exhibit No. 2.)
Q. BY MR. MANDELL: Have you ever seen this document?
A. Yes.
Q. When do you recall first seeing it?
A. Monday. It was an email.
Q. After you received this deposition notice, did you go search for any documents to bring with you here today?
MS. SCARCELLO: I'll object just in general to the notice and incorporate by reference our -- the responses and objections that we filed earlier in response to this notice of deposition.
Subject to those objections, you can answer whether you looked for any documents.
A. I did.
Q. BY MR. MANDELL: Okay.
A. I didn't find them, either.
Q. Okay.
A. Dang. I was going to look for my first deposition, but I didn't find it.
Q. Rather than going through the exercise of going

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through each one of these requests you can see on the final three pages of this Exhibit 2, it's my understanding that you did look for each of these things and you did not find anything responsive?
A. I did look for each of these things?
Q. Yes.
A. No. I absolutely did not. No.
Q. Understanding that you didn't go through each one of these, the answer would be that you did not search for documents for each one of these requests?
A. I did not. I was a little crazy after I saw that.
Q. Okay. No problem.
A. Okay.
Q. Let's start with the injuries you are alleging in this case against my client.
Strike that.
Let me go ahead and introduce as Exhibit 3 your medical records from the Oregon Clinic.
(Marked Deposition Exhibit No. 3.)
Q. BY MR. MANDELL: These are Bates labeled MDR1 to 37. We'll be using those page numbers on the bottom right-hand corner to discuss those.
Do you understand that?
A. Uh-huh. Thank you.
Q. I'll hand that over to you. If you go to --

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MS. SCARCELLO: Do you have a copy?
MR. MANDELL: Yes, I do. Sorry.
Q. BY MR. MANDELL: Just for the record, on page 1 there's a certification that these records are true and correct copies as of 2-28-2019 of Ms. Smith's records for the Oregon Clinic. We'll come back to these later, Ms. Smith.
A. I have to tell you this is very curious. I'm glad you have these. I don't.
MS. SCARCELLO: Can we go off the record for a second?
MR. MANDELL: Sure.
(Discussion off the record.)
Q. BY MR. MANDELL: Ms. Smith, let's start with the injuries you are alleging in this case against my client. My understanding is that it's, one, pelvic/vaginal pain and, two, pain with sex.
Is that correct?
MS. SCARCELLO: I'll object to the question to the extent that it could have been and probably was asked and answered in the 2017 deposition. You know, whether there's any update I think is a fair question, but to that question as stated, I would direct her not to answer.
(Instruction not to answer.)

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Q. BY MR. MANDELL: Are you going to listen to your counsel's recommendation there?
A. Yes.
Q. Since 2017, your last deposition in 2017, my understanding is that your injuries are, one, pelvic and vaginal pain and, two, pain with sex.
Is that correct?
A. Those are my two complaints. I also have a third complaint that is bowel pressure that is difficult to control, walking, whatever. I'm not sure if I discussed that earlier. That is also an issue.
Q. Now --
A. So the pain is, like, all the time. It's pelvic pain that is constant. Then the sexual pain is so severe that it causes you not to have sex.
Q. Right. We'll address those injuries separately.
A. Okay.
Q. Now, since your explant in 2018, are those three complaints, pelvic pain, sexual pain, and complaint with bowel pressure and control, still occurring?
A. Yes.
Q. Anything else?
A. I don't think so.
Q. So let's start with the pelvic pain and vaginal pain. Your Exhibit 1 indicated the -- the plaintiff

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fact sheet indicated that you still suffer from pelvic pain and vaginal pain.
Is that correct?
A. Yes.
Q. Have your symptoms lessened after the explant surgery in 2018?
A. Yes, they have.
Q. How have they lessened?
A. The constant ache in my pelvic area has lessened. It still is tender. It's sore. I still have to move around when I'm sitting. I have to sit on a pillow. So they've lessened.
Q. After the explant and currently now, on a scale of one to ten, what are you saying the pain is at?
A. Three to four.
Q. Now, you previously had testified to what the pain felt like up to your April 2017 deposition. I'm just trying to understand.
Is it the same type of sensation that you felt before that you described in your April 2017 deposition?
A. We're talking about the same area, the same pain. It's just lessened.
Q. Okay.
A. If I remember correctly, I think I said I was at a

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four, and I probably should have said five or six. I was still in denial about how much it hurt, what the pain really was.
Q. Currently where does this -- if you were to be specific, where does this pain originate?
A. Very low in my vaginal area and the very bottom back. So I can sit on it.
Q. Does this pain spread elsewhere?
A. It doesn't ever come up top. It's very low.
Q. It's specific and localized?
A. Yes. I believe so.
Q. How long does the pain last?
A. It's always there.
Q. Is it always the same or does it -- do you have some days better than other days or sometimes are better than other times?
A. I think if I am very active I notice it more. It feels heavier, like my butt is going to fall off. Sorry. I don't know how else to describe it.
Q. Does laying down help?
A. No.
Q. Let's focus on the pelvic and vaginal pain before your explant in November of '18. In your April 2017 deposition, you testified to the type of vaginal pelvic pain you had, the duration and sensation. I

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don't want to revisit that again.
Let's start with this. What was your pain on a scale of one to ten, three months before your explant?
A. I would say it's five or six.
Q. Would you say that pain level was the same level of pain you had from April 2017, at the time of your deposition, until your explant in November of 2018?
A. Yes.
Q. I've got to tell you I have a record here that says -- if you turn to Exhibit 3, MDR17, it says here that your pain is a two out of ten, and that was recorded three months prior to your explant.
Do you see that? It's under History of Present Illness.
A. Where was this done? The Oregon Clinic?
Q. Yes. This is August 23, 2018, about three months before your explant.
A. Well, my pain is higher than two now, so I guess I could just explain this off by saying that I was super nervous about going. I felt like -- I don't know. I felt guilty about this whole process of having had the implant, and it was causing so many problems for us. I tend to downplay my pain and whatnot even to my doctors.

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Q. Now, before your explant, did any healthcare provider ever tell you that your pelvic and vaginal pain was related to your mesh?
MS. SCARCELLO: I'll object to the question to the extent it calls for testimony that could have been provided in April 2017.
Q. BY MR. MANDELL: I'll limit it. From 2017 to before your explant in 2018, did any doctor say that your pelvic and vaginal pain was related to your mesh?
A. When I went to Nikki Kuehl and I asked her specifically if my pain could be from that, she said she didn't know and that she would need to -- you know, she sent me to Lindsey Waugh at the Oregon Clinic, and in that visit she said that it could be caused from that.
Q. That was Dr. Waugh?
A. Uh-huh.
Q. Anyone else other than Dr. Waugh say --
A. It's Waugh, W-A-U-G-H.
Q. Anyone else other than Dr. Waugh say that the mesh could be the cause of your pelvic and vaginal pain?
A. The person who did the excision, Dr. Denman.
Q. Anyone else?
A. No.
Q. Did Dr. Denman or Dr. Waugh ever tell you that the

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pelvic and vaginal pain was related to a defect in your mesh?
A. No.
Q. Did any physician ever tell you that the pelvic and vaginal pain you experienced from 2017 to 2018 was related to a defect in your mesh?
A. No. I had no idea about a mesh defect.
Q. Did any physician ever tell you that your pelvic and vaginal pain that you felt before the explant was Bard's fault?
MS. SCARCELLO: I'll object to the form of the question. It could have been asked in the 2017 deposition.
And direct you not to answer.
(Instruction not to answer.)
Q. BY MR. MANDELL: Between 2017 and your explant in 2018, did any physician tell you that the pelvic and vaginal pain you felt before the explant was Bard's fault?
A. Absolutely not.
Q. When you go to your doctors, do you feel comfortable speaking to them?
A. Mostly.
Q. You agree it's important for you to tell your doctors everything about your condition in order for

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them to properly diagnose you, correct?
A. I understand that, but I don't think it always happens. I know it doesn't always happen.
Q. Do you ever lie to your doctors?
MS. SCARCELLO: I'll object to the form of the question. Again, I'll state this deposition is supposed to be limited from April of 2017 forward. To the extent your question calls for an answer about anything prior to that time period, I would direct my client not to answer.
MR. MANDELL: I'm just asking if she ever lies to her doctors. If you want me to specify --
Q. BY MR MANDELL: Between 2017 to 2018 -- to currently, have you ever lied to your doctors?
A. I haven't lied. No. Have I misstated? Have I understated the situation? Yes. I believe I have.
Q. When you go to the doctor, do you tell the doctor the whole and complete truth about everything that you are dealing with physically at the time?
A. I think that would be difficult to do.
Q. Do you tell your doctor any -- all the physical pain you may be having at the time?
A. No. It's usually something specific that we're talking about, so I don't take notes with me, so it's easy to forget what you wanted to say.

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Q. Just to clarify, you indicated that sometimes you misstate things to your doctor. What is the reasoning behind that?
MS. SCARCELLO: I'll object to the form. It misstates her testimony.
Go ahead and answer.
A. As I said before -- for instance, when I said here that I have a pain of a two, there's -- I don't even think people would go to the doctor for a pain of just two. In my head that's what I'm thinking.
When I was sitting there talking to her, I really was nervous. Maybe at that moment the pain was two because I wasn't really thinking about it. But I can tell you that in general it's a four, three or four.
Q. So in general, from April 2017 to your explant, it was a three or four?
A. Yes.
Q. We're talking about the pain in -- your pelvic and vaginal pain, correct?
A. Yes.
Q. Since your explant in 2018, has any physician ever told you that the current issue that you have of pelvic and vaginal pain is related to your mesh?
A. Including the doctor that just took the mesh out?

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Q. Let me rephrase that. You had an explant procedure to remove the mesh, correct?
A. Again. Yes.
Q. So has any doctor since then said that your current pain with -- pelvic and vaginal pain is still related to mesh?
A. The pain is the same. It has not changed. We haven't spoken those words exactly, so I guess no.
Q. Has any physician ever told you that your current pain -- pelvic and vaginal pain is Bard's fault?
A. No.
Q. Now let's focus on the pain with sex that you claim is one of your injuries.
Okay?
A. Yes.
Q. You previously testified to pain with intercourse. This was in April 2017. Are those symptoms the same as you described in 2017, the sharp deep pain when having intercourse, the same as they were from 2017 to your explant?
A. Absolutely.
Q. So no changes, whether that be worse or better?
A. Same.
Q. Did the frequency of your sex change at all from April 2017 to the explant in November 2018?

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A. No.
Q. Then you had the November 2018 explant surgery. Did this improve your symptoms of pain with sex in any way?
A. It did not improve it. No. It made it worse.
Q. So since the explant surgery in 2018, the pain with sex has actually --
A. Actually, not the pain. The pain has -- is maybe slightly less. But I don't believe it is. But now I bleed. Now I have bleeding with it.
Q. Let's explore -- let's start first with you said maybe slightly less. On a scale of one to ten, what would you say it is currently?
A. You know, I have to say I haven't practiced very much. I've been in treatment since November. I have not healed properly, and I'm still in treatment. So sex has happened three or four times. So I'm always not supposed to have it.
Q. Let's start with this then. After the explant surgery in November 2018, when did you first attempt to have intercourse?
A. Whenever the doctor said it was -- what was it? After a month, and that didn't work, so maybe two months.
Q. So you waited two months to have -- before you had

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intercourse after your explant surgery; is that correct?
A. I believe so. It's either eight or ten weeks, and I'm not sure. I think -- now that I think about it, I think it was ten weeks.
Q. So ten weeks?
A. Yeah.
Q. Can you describe to me what occurred when you had -- as far as -- strike that.
Did you feel pain at this first attempt of intercourse ten weeks after your explant surgery?
A. Yes.
Q. Can you describe to me how that was either the same, different -- same or different from how you described the pain in April 2017 with intercourse?
A. I'm going to say it was slightly less, slightly less pain.
Q. But the same location?
A. Same place. Yes.
Q. The same sensation; is that correct?
A. Deep. Yes.
Q. I believe you described it as a deep sharp pain, so that's the same?
A. Uh-huh.
MS. SCARCELLO: Is that a "yes"?

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A. Yes, it is.
Thank you.
Q. BY MR. MANDELL: After this first attempt ten weeks after the explant, have you -- did you try intercourse again after that?
A. After I went to the doctor and another two weeks. You know, I don't remember. Whatever the doctor said. She laid it out for me. We followed her guidelines specifically.
Q. So ten weeks after the explant you attempted intercourse and you felt pain. Did you then go to your doctor to report that?
A. I did not go -- I went again, but I'm not sure if it was right then. So I did see her again.
Q. Did you -- when you saw her again, did you report any pain with sex?
A. Uh-huh.
MS. SCARCELLO: Is that a "yes"?
A. Yes, it is.
Q. BY MR. MANDELL: This is Dr. Denman, correct?
A. Uh-huh. Yes.
Q. What did Dr. Denman say in response to that?
A. To the pain?
Q. Yes.
A. She said, you know, I'm glad it's less, but there's

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still, you know, mesh in there, so -- we got a lot of it out, so there might be, you know, more. Well, she knows there's more. I don't know. I was more worried about the bleeding. When she looked, I wasn't healed. That's another big deal.
Q. This issue of bleeding, when did this -- when did you first notice this, the bleeding with having intercourse? When was the first time you noticed that?
A. First time we had intercourse.
Q. Ten weeks after the explant?
A. Uh-huh. We're talking just with intercourse, right?
Q. Right.
A. Uh-huh.
Q. Since the explant surgery in 2018, can you estimate the number of times you attempted to have sexual intercourse?
A. I guess six.
Q. Are you currently sexually active?
A. I'd love to be, but I'm not now because I'm healing from the last surgery.
Q. You are healing from the November 2018 surgery?
A. Yes. I'm still bleeding. It's still not healed.
Q. In your last deposition, you testified that you were still -- I'm sorry to get into the private nature of

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this stuff -- you were still able to achieve orgasm despite the pain you were feeling.
Was that true as well from April of 2017 to the explant in 2018?
A. Absolutely.
Q. What about currently? Are you still able to achieve orgasm on any of the six times that you attempted after your explant?
A. Not through intercourse.
Q. But you were able to achieve orgasm through intercourse prior to the explant?
A. I'm going to say no. Nobody asked me specifically like that.
Q. So it's my understanding through other types of sexual activity you are able to achieve orgasm; is that correct?
A. Yes. That's correct.
Q. That was the case since your April 2017 deposition as well as currently?
A. Yes. I'm sorry. I had to think about that.
Q. Other than Dr. Denman, since your 2018 explant, have you reported pain with sexual intercourse to any other healthcare providers?
A. I haven't seen any others.
Q. At any time before your explant in 2018, excluding

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your post-op recovery from the -- strike that.
At any time before your implant, excluding your post-op recovery from the implant and the revision that you had, did any doctor ever tell you to limit your sexual activity?
MS. SCARCELLO: I'll object to that to the extent of the time frame before her implant and before April of 2017 could have been asked in April 2017.
Direct you not to answer.
(Instruction not to answer.)
Q. BY MR. MANDELL: Let me rephrase it without using too many words. Since April 2017 to the time of your explant, did any doctor say -- tell you to limit your sexual activity?
A. Let me answer it this way. The only doctors who have said at any time to limit my sexual activity was after surgery and while I was healing.
Does that answer the question?
Q. It does.
A. Okay.
Q. So no doctor since 2017 to now has ever told you that you could not have intercourse, excluding the post-op recovery?
A. Yes.

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Q. Have you or your spouse since April 2017 ever been treated for sexual dysfunction?
A. No.
Q. Focusing on the time after April 2017, would you say -- from then until currently, is your marriage still strong?
A. It's a struggle, but it's strong. It's a struggle.
Q. Would you describe it as a loving relationship?
A. Absolutely.
Q. Today do you feel as much love towards your husband as you did when you first got married?
A. Yes.
Q. Now, I saw in a record -- a recent record that your husband had a pulmonary embolism, correct?
A. Yes.
Q. When was that?
A. A couple years ago.
Q. How was your husband treated?
A. How was he treated? He went to the hospital. He had some -- he had a CT scan. He had some stuff happening. The doctor there -- I don't know. I'm nervous. I don't know. I can't think.
Q. No problem.
MS. SCARCELLO: Can we take a break?
MR. MANDELL: Sure. We can take a break.

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(Recess.)
Q. BY MR. MANDELL: I was discussing with you your husband's pulmonary embolism. Did that have any effect on his ability to do any physical activities after he had that pulmonary embolism?
A. Not in general. No.
Q. Has it affected his ability to have sex at all?
A. No.
Q. Before your explant, so focusing on April 2017 to your explant, did any physician ever tell you that your pain with sex was related to your mesh?
A. Yes. That's what Dr. Waugh says. Yes. Absolutely.
Q. So Dr. Waugh. Anyone else?
A. Dr. Denman. And they were assuming that was the case.
Q. Those were the only two healthcare providers, correct?
A. (Nods head.)
Q. Did either of those doctors or any other doctor tell you that the sharp pain you felt with sex was related to a defect in your mesh?
A. No.
Q. Did any physician ever tell you from 2017 to the explant that the pain with sex that you felt was Bard's fault?

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A. No.
Q. Since your explant in November 2018, has any physician ever told you that your current issue with pain with sex is related to your mesh?
A. Can you say that again, please?
Q. Since your explant, has any physician ever told you that the current issue you have with pain with sex was related to your mesh?
A. It's the same issue, so yes.
Q. Which healthcare provider has told you that your current issue of pain with sex is still related to the mesh?
A. It would be Dr. Denman. She's the only one I've seen. Can I just say that I'm not sure if she said those words exactly, but I assume that's the case. It has to do with the mesh because I'm still healing from it. So that's what I'm saying, the whole mesh.
Q. To clarify, your assumption is that your pain with sex is still related to your mesh because you are still feeling the same pain, correct?
A. Yes.
Q. But no doctor has specifically told you that your current pain with sex is related to the mesh; is that correct?
A. I'm not sure.

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Q. Since your explant, has any doctor said that your current pain with sex is due to a defect with the mesh?
A. No.
Q. Since your explant, has any physician ever told you that your current issue with pain with sex is Bard's fault?
A. No.
Q. The third injury that you brought up was an issue with bowel incontinence and pressure?
A. Uh-huh.
Q. Is that a "yes"?
A. Yes.
Q. Now I want to direct your attention to Exhibit 3, page -- Bates page starting on 11. Do you see that in the bottom right-hand corner?
A. Yes.
Q. Now, it says here -- let's actually turn to page 12 where -- this is a record of Dr. Denman on August 29, 2018, and she's discussing your history of present illness.
If we go to page 12, it says in the third line, "She does have issues with bowel incontinence."
Do you see that?
A. Uh-huh. "She does have incontinence of urine."

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Q. "She does not have incontinence of urine."
A. "She does have issues with bowel incontinence."
Q. "However, that has been becoming more troublesome. She leaks liquid solid stool about once per week. She has this issue when walking. She has not done anything about this."
Did I read that correctly?
A. You are a good reader.
Q. So the answer is "yes"?
A. Yes.
Q. Would I be correct in saying this is the first time you reported to a healthcare provider having any type of bowel issues?
A. Yes.
Q. Would I be correct in saying that these bowel issues occurred somewhere along -- somewhere around this time of August 29, 2018?
A. They've been coming on. I just -- in my mind, I wasn't really sure if that was -- it's all in the same area. So I finally decided I would talk about that issue as well and maybe it has something to do with it. I don't know.
Q. Let me ask you this. When did you first start having symptoms of bowel incontinence and pressure?
A. It's been going on for years.

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Q. When you say years, when exactly?
A. I don't know.
Q. Has it been going on the last three years?
A. Yes.
Q. More than three years?
A. More than likely. Yes.
Q. More than five years?
A. I think it's becoming worse and worse over that period of time.
Q. Has it occurred -- has it been occurring for ten years?
A. Not that I recall. Like I said, it's been getting worse and worse.
Q. Do you recall having any symptoms of it prior to your 2008 implant?
A. I don't.
Q. Now let's go back to Exhibit 3, page 11. You'll see under Plan, No. 2, it says, "FI," which I'll represent to you means fecal incontinence, which is --
A. Lovely.
Q. -- the bowel pressure that we're discussing.
You understand that?
It says, "Discussed likely nerve damage for FAVD," which I'll tell you stands for forceps

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assisted vaginal delivery, "/episiotomy with delivery."
Let me stop right there. Did you have a forceps assisted delivery at some point?
A. Yes, I did. 1977.
Q. Then it says, "Discussed initial management with fiber for bulking and possible change to Imodium if not optimal control."
Do you see that?
A. Uh-huh.
Q. Then it says, "Reassurance, there is not a mesh factor involved in the issue."
Do you see that?
A. Yes.
Q. So Dr. Denman told you that this bowel incontinence and bowel pressure injury you are complaining about is not related to the mesh; is that true?
A. I did not hear that verbatim. No. We did say we were going to try bulking up, but that changed nothing.
Q. Now, after seeing this record, do you still believe that your bowel incontinence and bowel pressure is related to your mesh?
A. It could be.
Q. Has any doctor told you that?

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A. Uh-huh.
Q. Is that a "no"?
A. I don't recall.
Q. Your belief that it could be an injury related to the mesh is simply because it's in the same general area as your other injuries you are claiming; is that correct?
A. I'm saying that it could be involved. Yes.
Q. But to your recollection, no healthcare provider has told you that the mesh is causing these current issues of bowel pressure and incontinence; is that correct?
MS. SCARCELLO: Object to the form of the question; asked and answered.
You can answer.
A. I'm sorry. I forgot the question already.
MR. MANDELL: You can read it back.
(The reporter read the last question.)
A. I'm just going to say I did not hear that.
Q. BY MR. MANDELL: Okay.
A. If they told me that, I did not hear that.
Q. Do you recall in your last deposition testifying that Dr. Kim told you that you may have problems defecating later on down the road?
A. I don't recall.

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Q. Do you recall her ever diagnosing you with rectocele?
A. I don't even know what that is.
Q. Do you recall -- let me -- I'm going to read from your deposition transcript on this issue real quick. On page 49 -- we can introduce this as an exhibit if you'd like. Let's just do this as Exhibit 4.
(Marked Deposition Exhibit No. 4.)
Q. BY MR. MANDELL: If you turn to page 49, it says on line 13, "Can you tell me a bit about the discussions you had with Dr. Kim?"
Your answer was, "It was very interesting. I went in and she, you know, asked about my incontinence and I said, yeah."
I'm going to skip down a little bit and go to --
A. What were you saying was so interesting? My answer? What are you talking about?
Q. I was having you follow along with me. I want you to turn to the next page, on page 50, and it says on line 5, "She asked if I had problems defecating, and I said, not so much. And she said, well, you know, that might be an issue down the road."
Do you see that?
A. Yes. And I do remember her saying that now.

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Q. Then on line 10 it asks, "So what do you mean by she thought defecating might be an issue down the road?"
Do you see that?
A. Yes. I'm following.
Q. If we go to line 16, you said, "So I don't think she treated the -- you know, for not being able to have a great bowel movement, but that was part of the conversation."
Do you see that?
A. Uh-huh.
Q. Is it your understanding then that you were not treated for the bowel issues that Dr. Kim said you may have later on down the road?
A. No. I don't actually see that as conclusive. No.
Q. Do you believe you were treated by Dr. Kim for bowel issues?
A. I'm not sure.
Q. Now, you testified here, "So I don't think she treated me, you know, for not being able to have a great bowel movement."
Is it your understanding from your testimony here you don't think she treated you?
A. It sounds like I wasn't sure. I'm still not sure.
Q. You are still not sure if the mesh is the reason for these bowel issues currently, right?

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A. I hate my mesh, and I feel like it is a very -- could be the problem that I have. Absolutely.
Q. All right. Since we're talking about this, let's discuss a little bit. The symptoms with the bowel issues, can you describe those for me?
A. When I walk or I'm standing -- it's really walking. Even if I have a bowel movement before I leave the house, before I get too far, oftentimes, it's not 100 percent of the time, but I would say 85 or 90 percent of the time I have to have a bowel movement. I have to cut the walk short, head back home.
Q. This has been from -- correct me if I'm wrong. This has been something that has progressively gotten worse since you first started noticing it; is that correct?
A. Uh-huh. Yes.
Q. Your description that you just gave me is your current symptoms, right?
A. Yes.
Q. Was there any change in your symptoms that you currently have -- was there any change from the explant procedure? Did the symptoms get better or worse or stay the same after the explant procedure, is a better way of asking it?
A. They have gotten better.

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Q. We're talking about the bowel issues.
A. Yeah. And I -- yes. They have gotten better. Now that I think about it, they actually have gotten better.
Q. How have they gotten better?
A. I can walk much more often now without having to come back. Probably 60 percent of the time I can finish the walk. Or I can come back -- I have to come back. Forty percent of the time I can finish.
Q. Now I'm confused because you just said 80 to 90 percent of time you can't finish the walk.
A. Right. Now I'm going to say 60 percent of the time. When you said before, I mean before the explant. So when you say currently, I guess that means right now it's better at I would say 60 percent.
Q. Do you have any pain associated with this?
A. No. Just pressure. No pain.
Q. Can you describe the pressure? We'll start with location.
A. It's in my bowels, my anus.
Q. Is it a constant pressure? Does it come and go?
A. No. It's constant.
Q. I think that's fine for that. All right.
Other than your 2018 surgery with Dr. Denman, did you seek treatment for any of these conditions

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we discussed?
A. When are you talking about?
Q. Let me clarify. We've been going over the three injuries that you claim may be related to the mesh, which were pelvic vaginal pain, pain with sex, and these bowel incontinence issues and pressure, correct?
A. Uh-huh.
Q. Other than your 2018 surgery with Dr. Denman, did you seek treatment for any of these conditions since then?
A. When I went back to see Dr. Denman. Yes.
Q. So just Dr. Denman has treated --
A. Just Dr. Denman.
Q. You've not seen any other doctors for these issues?
A. No.
Q. Did anyone assist you with scheduling an appointment with the physicians at the Oregon Clinic, including Dr. Denman?
A. Sorry?
Q. Did anyone assist you with scheduling your appointments at the Oregon Clinic?
A. Anyone like who?
Q. Anyone other than --
A. A physician?

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Q. -- a physician?
A. No.
Q. Has anyone assisted in paying for your treatment at the Oregon Clinic?
A. No.
Q. Anyone arrange for travel costs associated with your treatment to the Oregon Clinic in Portland?
A. No.
Q. Since your explant, has it been recommended that you try physical therapy?
A. No. We talked about that might -- being an issue, but that -- it does not happen. No.
Q. My question, though was, has anyone recommended that you do physical therapy?
A. No. We've talked about it, but it's not recommended yet, if it's going to be.
Q. Has anyone since your 2018 explant recommended any type of pain management therapy?
A. No.
Q. Have they recommended any type of pain medicines?
A. No.
Q. Have they recommended any type of trigger point injections?
A. No.
Q. Are you doing anything currently on the advice of a

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physician or on your own initiative to get better?
A. Yes.
Q. What is that?
A. I'm taking the medication that has been provided or suggested that I take. I eat well. I try to walk, try to exercise by walking. I don't drink very much. I don't smoke. I try to be happy.
Q. You indicated you are taking the medication. Is that an estrogen medication?
A. Uh-huh.
Q. Has that been helping at all?
A. I don't know.
Q. Are you still taking that today? Is that correct?
A. Yes.
Q. You were prescribed that by Dr. Denman; is that correct?
A. Yes.
Q. You started taking that sometime -- did you start taking that immediately after your explant surgery?
A. Sometime after that. Yes. Whenever it was prescribed.
Q. So from your records I can see that since your 2017 deposition you continue to be treated for depression, numbness and tingling in your hands and feet, carpal tunnel syndrome, pain and tingling in

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your arms?
A. I'm not being treated for that. I had a study done, and I decided not to do anything about it because this is so consuming. Yes. I have depression medicine still.
Q. The study done, you are referring to the numbness and tingling that you are having?
A. Uh-huh.
MS. SCARCELLO: Yes?
A. Yes. Sorry.
Q. BY MR. MANDELL: Tell me what happened with the study.
A. I had the study done. Previously I had carpal tunnel in this hand and had surgery on it, so I actually knew what was going to happen with this hand. So I went in and I had the study done. She said, yes, I have carpal tunnel.
I just didn't have enough finances basically to do the treatment, and I just decided to suffer through that stuff.
Q. This is Dr. Barbara Hills; is that correct?
A. I believe so. Yes.
Q. It looks like this occurred -- the study occurred in September 2018; is that right?
A. Uh-huh.

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MS. SCARCELLO: Is that a "yes"?
A. Yes.
Q. BY MR. MANDELL: So you still have these symptoms today of carpal tunnel syndrome; is that right?
A. Yes.
Q. Are you planning on having any type of treatment or surgery for that?
A. I don't know.
Q. Has the carpal tunnel syndrome that you still have today put any physical limitations on you?
A. Yes. I mean I have to sew less. I have to, you know, drive less, switch my hands around. I have compensated.
Q. Has it affected your ability to exercise?
A. No.
Q. How about kayaking?
A. No.
Q. Any activities other than what you've told me that you've had to compensate for, that you cannot do anymore because of the carpal tunnel syndrome?
A. No.
Q. I know there was some mentioning of pain and tingling in your arms. Is that something you also feel or is it just the carpal tunnel?
A. Carpal tunnel all the way. It's all the same thing.

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Q. You were diagnosed with depression prior to your implant; is that correct?
A. Yes.
Q. It stills continues to this day; is that correct?
A. That's correct.
Q. What medication do you currently take?
A. I take Lexapro and Wellbutrin.
Q. How long have you been taking those for?
A. Lexapro over ten years, maybe 15 years, and the Wellbutrin just in the last year or so, I believe.
Q. What was the reason for adding on the Wellbutrin?
A. My depression symptoms are still there. So Dr. Kuehl and I talked about what else could happen, especially since I couldn't exercise, so I added the Wellbutrin.
Q. Nurse practitioner Kuehl prescribed that; is that correct?
A. Yes.
Q. You said your symptoms of depression. What are those symptoms?
MS. SCARCELLO: I'll object to the form of the question just in terms of it's vague in terms of time frame. Are we talking 2017 forward?
Q. BY MR. MANDELL: Yes. We're talking about 2017 forward. You indicated you were still having

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depression symptoms, which is why you took Wellbutrin, so I'm just asking you to explain what those depression symptoms were?
A. It's hard to tell I've been taking it for so long. If I don't take it, I can tell you what the symptoms are. I'm very dizzy, lightheaded. I have confused thinking, very tired, irritable. There's probably a whole lot more things I can't think about.
Q. Have you been consistently taking your medication since April 2017 to today?
A. Yes.
Q. Now, if we go to Exhibit 3, let's go to page 2, MDR2, it says here -- this is an August 13, 2018, visit with nurse practitioner Kuehl.
Do you see that?
A. Uh-huh.
Q. Is that a "yes"?
A. Yes.
Q. It notes here, it looks like, the third dash, "Has been using Lexapro 20 milligrams a day for over ten years for depression."
Do you see that?
A. Uh-huh.
MS. SCARCELLO: Is that a "yes"?
A. Yes.

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Q. BY MR. MANDELL: The next sentence says, "For the past year she has felt depression increasing again. Her head feels heavy and she feels sluggish and irritable."
Is that correct?
A. Those are more symptoms. Absolutely.
Q. Is that a symptom of your medicine that you are taking or a symptom of the depression?
A. Pardon me?
Q. It says your head feels heavy and she feels sluggish and irritable.
A. I see your question. This is in addition to the Lexapro. That's why I went in initially is to just say this just isn't enough. I just feel really terrible.
Is that the answer?
Q. I think I understand it now. This is when you went in to get the Wellbutrin, right?
A. Yes, it is. Well, to see if it should change. I've been taking it for a long time. I don't know if that makes a difference.
Q. Up around this time in August 13, 2018, you'd agree that you were feeling sluggish, correct, as noted here?
A. Yes.

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Q. The sluggishness, you would agree that would affect your ability to do certain activities like exercising?
A. No. It's -- no.
Q. If you feel sluggish, what activities does it prevent you from doing?
A. You can still walk. It doesn't matter how tired you are or whatever. It's a walk. Feeling sluggish is kind of in your head and it's less -- it doesn't let you think well. Yeah. I don't know. It didn't stop me from doing anything.
Q. Would you agree that your energy felt lower when you felt sluggish?
A. Probably. Yes.
Q. Now, you previously testified to saying that your mesh implant has lowered your energy, which was the reason why you couldn't hike and kayak.
Do you recall saying that?
A. Sure.
Q. I'm asking you here, because your energy was lower at this time, is that an additional reason why you might not have been able to hike and kayak?
A. No. This is different.
Q. Do you believe that this sluggishness that you are feeling at this time prevented you from doing any

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sort of activities at all?
A. No.
Q. Do you still have anemia?
A. No.
Q. It looks like you were diagnosed with low back pain in 2005. Is that something you still feel today?
A. No.
Q. Since your 2017 deposition, have you been diagnosed or treated for any cardiac or pulmonary issues?
A. No.
Q. Kidney or thyroid issues?
A. No.
Q. Cancer?
A. No.
Q. Blood pressure issues?
A. No.
Q. Diabetes?
A. No.
Q. Any back, neck or spine issues?
A. No.
Q. Fibromyalgia?
A. No.
Q. Since April 2017, have you been involved in any motor vehicle accidents?
A. No.

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Q. Any broken bones?
A. No.
Q. Any significant surgeries other than the explant in 2018?
A. No.
Q. Any accidents or injuries for which you needed stitches?
A. No.
Q. Are you still good to go or do you need a break?
A. I'm good. Thank you.
Q. At your last deposition you indicated you were seeing nurse practitioner Nikki Kuehl who put you on estrogen to try to address what you described as an aching in your pelvis.
Do you recall that?
A. Yes.
Q. You indicated you were on the estrogen regimen for about a month at that time. Do you recall that?
A. Huh-uh.
Q. So that's a "no"?
A. That's a "no."
Q. Nurse practitioner Kuehl had prescribed you estrogen. How long did you take this estrogen that she prescribed you back in March of 2017?
MS. SCARCELLO: I'll object to the time frame

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of your question.
MR. MANDELL: We didn't have this record at the time of the deposition.
MS. SCARCELLO: Okay. My position -- it's our position that not having the record doesn't mean that you couldn't have asked questions about her ongoing treatment at that time. Subject to that, I'll allow her to answer.
Q. BY MR. MANDELL: I'm just briefly going to go over this stuff. She prescribed it to you in March of 2017. How long did you take it for?
A. I assume I took it for as long as she prescribed it.
Q. In this record, Ms. Kuehl discusses about you seeing a Dr. Gerken, an ob/gyn, for a steroid injection.
Do you recall that?
A. We talked about it.
Q. Did you ever go see Dr. Gerken?
A. No.
Q. Why not?
A. I don't remember.
Q. Did you ever have steroid injections at any point before the November 2018 surgery?
A. No.
Q. Were they offered to you by any other doctors from April 2017 to your 2018 explant surgery?

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A. I had one steroid injection in my life, and it was in my wrist. So no and no. I don't even know what a steroid would be for. I'm confused.
Q. Is there any reason why you did not return to Dr. Kim for treatment around this time of April 2017?
A. I wanted a new doctor. She was not -- she's not who my doctor suggested, so I didn't have -- it's been a long time since I'd seen her, so I didn't really feel like I was a patient.
MS. SCARCELLO: Can we take a break?
MR. MANDELL: Sure.
(Recess.)
Q. BY MR. MANDELL: I just wanted to actually pull your attention back to Exhibit 1, the plaintiff fact sheet that you filled out in February of this year. Go to page 7, which is Bates labeled at the very bottom 105.
It says in part E, "Are you currently experiencing symptoms related to your claimed bodily injuries?" And you say, "Yes."
I don't see anywhere here any discussion about bowel incontinence or pressure. Do you see anything there about that?
A. No.

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Q. Looking at your claims again, are you still claiming that bowel incontinence, pressure is part of your injuries related to mesh in this lawsuit?
A. It could be.
Q. So you don't know one way or the other; is that correct?
A. I don't know one way or the other.
Q. I want to go back to Exhibit 3, the medical records. If we go to page 2, this is your August -- this is MDR2, August 13, 2018, visit with nurse practitioner Nikki Kuehl.
Am I stating that correctly?
A. Yes.
Q. My only question for you here is, on the third page it says, "Breast and pelvic exam: Declined." Do you recall why a pelvic exam was declined at this time?
A. It's for a pap smear and I don't need one. I don't have a need for that.
Q. In this record it does say that on page 2 you are experiencing vaginal pain and the mesh was trimmed one year after procedure which did not resolve the pain.
Do you see that?
A. Uh-huh.

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Q. Is that a "yes"?
A. Yes.
Q. And that is something that you reported to Ms. Kuehl; is that right?
A. Yes.
Q. She didn't perform an exam at this time to determine if you were having pain; is that correct?
A. She would not have had to do that. Correct. I told her there was pain.
Q. Would I be correct that this is the first time that you reported the vaginal pain that you were having since the 2009 excision?
A. I don't know.
Q. Would this be the first time that you saw a healthcare provider for vaginal or pelvic pain following the 2009 excision?
A. I don't know. Don't recall.
Q. Now let's go to the next record here on -- it's actually on page 17, MDR17. This is August 23, 2018.
Are you there?
A. Yes.
Q. This is -- it says office visit with Lindsey Waugh, Dr. Waugh, right? Is that correct?
A. I believe so. Yes.

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Q. It states under History and Present Illness, "States that she had a bladder sling placed and hysterectomy around 2008, thinks Adventist, since then she has a constant dull pain especially with intercourse."
Do you see that?
A. Yes.
Q. That's what you told Dr. Waugh, that your vaginal pain and pain with sex started in 2008, right?
A. Yes.
Q. And this is the same pain you claim to have leading up to your explant performed in November 2018, correct?
A. Yes.
Q. The same pain you claim to currently experience?
A. The same area. The pain is not quite the same.
Q. That's because the pain has actually decreased since the explant; is that right?
A. Slightly. Yes.
Q. It says here you've been claiming this pain since 2008. Do you know who you went to go see for that pain?
A. No. In 2009 I went to see Dr. Kim to have -- to see what the issue was. So I went to my physician maybe.
MS. SCARCELLO: I would object to the question

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to the extent we're discussing anything that happened prior to April of 2017.
A. Good.
Q. BY MR. MANDELL: What do you recall Dr. Waugh doing here on this office visit?
A. She did an exam.
Q. What type of exam did she do?
A. A vaginal exam.
Q. Can you describe to me what she did as far as the vaginal exam?
A. No.
Q. It indicates there that she palpated inside your vagina. Does that help refresh your memory?
A. No. It doesn't help.
Q. If I asked you where she palpated inside your vagina, would you be able to give me a response?
A. I know at one point she pushed where it hurt very much.
Q. Can you describe to me where she pushed?
A. Deep into my vaginal area.
Q. Right or left side, center?
A. Down low. I can't tell you anything else.
Q. No more specifics than that?
A. No.
Q. Did Dr. Waugh perform any other tests other than a

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vaginal exam?
A. I don't recall. I'm sorry.
Q. We're looking at page 17, right, Bates label 17?
A. Yes.
Q. It says here under History of Present Illness, if we go to the third paragraph, starting on the sentence that says sling, do you see that? "Sling is working great, no leaking"?
A. I don't.
Q. We're on MDR17. Under History of Present Illness, if we go to the third paragraph, second sentence.
A. Yes.
Q. "Sling is working great, no leaking."
Do you see that?
A. Uh-huh.
Q. Was that true at the time?
A. Right. I was not incontinent. Absolutely.
Q. Then it says, "Sexually active with single male partner. But has decreased frequency of intercourse due to pain."
Is that a true statement?
A. Absolutely.
Q. So you were having sex in August 23, 2018, correct?
A. I was sexually active to some degree.
Q. What frequency at this time were you having

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intercourse?
A. Very infrequently.
Q. Can you give me an estimate of how many times per week?
A. I could give you how many times per month, which is zero. How many times per quarter, maybe once. Maybe three or four times a year before this.
Q. So when it's reported here that you are sexually active, but the frequency is decreased, you are referring to these quarterly attempts; is that correct?
A. Uh-huh. Yes.
Q. This is all self reported by you? Do you understand that?
A. Yes.
Q. Now, it says -- let's go down to -- well, I'll read this. On the next line it says, "Pain is during deep penetration. Aching in nature. Pain worsens with different positions but is present all the time. Does not interfere with orgasm."
Is that all a true statement?
A. Yes.
Q. That's something I believe you testified to in your last deposition. Do you recall that?
A. No.

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Q. Now, on the second-to-the-last sentence, it says, "Does not use estrogen cream on a regular basis. Used estrogen for a while after mesh, not currently."
Is that a true statement?
A. It's a true statement.
Q. Why did you stop using estrogen cream?
A. It wasn't -- I wasn't seeing a physician at this time for this. So estrogen is not supposed to be used on a regular basis.
Q. When it says was using estrogen for a while after mesh, not currently, can you tell me what period of time you were using it?
MS. SCARCELLO: Object to the question to the extent it calls for testimony that could have been given in April of 2017 and direct you not to answer.
(Instruction not to answer.)
MR. MANDELL: I'm not quite sure it calls for that testimony. It depends what her answer is.
Q. BY MR. MANDELL: Let me ask you this. This is -- we're focusing on -- you had a visit in March of 2017 with nurse practitioner Nikki Kuehl where you said you were taking estrogen cream, and now we're in August 23 of 2018, and it's saying you are not.
I want to know what period of time you were

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taking it?
A. I think what it should have said was if I had taken it. I really don't recall if I was using it at that time. It has to be prescribed to you. It's not an over-the-counter.
Q. Understood.
A. So I'm not sure.
Q. Do you know if you completed whatever prescription prescribed from nurse practitioner Kuehl -- completed the course of treatment for estrogen cream? Do you know that?
A. I do know that. I did.
Q. On page 18 -- again, I apologize for going into the personal nature of these things, but it's involved with the claim of the case. It says here, "Partner has history of genital herpes."
Do you see that?
A. Uh-huh.
Q. It says, "Yes."
Is that correct?
A. That's correct.
Q. Has there been times where you did not have sexual activity because of your partner having an outbreak?
MS. SCARCELLO: I will object to the form of the question to the extent that it is asking for

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events prior to April of 2017.
Q. BY MR. MANDELL: Since April 2017, has there been any times where you did not have sexual intercourse because of your husband having an outbreak?
A. No.
Q. Would you have sexual intercourse with your husband if he did have an outbreak at the time?
A. No.
Q. How often does your husband have an outbreak of genital herpes, would you say?
A. In the last 15 years, none.
Q. Now, if we go to page 21, it says here under Plan --
Do you see that?
A. Yes.
Q. It says, "Discussed prolapse with regards to different compartments. Anterior prolapse continues to be well supported."
Do you see that?
A. Yes.
Q. You understand that your anterior prolapse was something that Dr. Kim treated you for with the Avaulta? Do you know that?
A. I couldn't have said that myself.
Q. Was it your understanding that that is what you were treated for by Dr. Kim?

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A. For the anterior prolapse?
Q. Yes.
A. Yes.
Q. It was still supporting your prolapse at this time; is that correct?
A. I don't understand the question. I don't know where we're at in the timeline here.
Q. We're still in August of 2018. Dr. Waugh is saying that your anterior prolapse continues to be well supported. I'm just asking you do you agree with that statement?
A. I trust her judgment.
Q. It says, "Posterior compartment to level of the hymenal ring."
Do you recall any discussion with Dr. Waugh about that?
A. No.
Q. Now, it says -- if we go down to the next little line, it says -- we'll go to the second sentence there. It says, "No evidence of mesh erosion on exam."
Do you recall Dr. Waugh telling you that?
A. Yes.
Q. Did you mention at this time to Dr. Waugh that you had a lawsuit pending regarding your mesh?

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A. No.
Q. It says here that he discussed meeting with -- it says here, "Discussed meeting with Dr. Batalden to consider mesh excision for pain reduction versus other options."
Do you see that under Plan?
A. Yes.
Q. Do you know what other options Dr. Waugh was referring to here?
A. I don't recall.
Q. Did you ever meet with Dr. Batalden?
A. No, I did not.
Q. Why not?
A. Because I met with Dr. Denman.
Q. So now you end up seeing another doctor, Dr. Denman, right? Is that correct?
A. Yes.
Q. The same symptoms we've been discussing about vaginal and pelvic pain and pain with sex, that's what led you to see Dr. Denman; is that correct?
A. Yes.
Q. Why did you -- strike that.
Can you tell me everything you can recall about the first time you visited Dr. Denman on August 29, 2018?

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A. I was -- I went to see her. I told her I had been -- she knew I had been referred from Dr. Waugh. We talked about what my symptoms were. I told her that I was just taking a last stab to see if there was something that could be done about the pain so I didn't have to live with it for the rest of my life. As well as my sexual activity being, you know, completely curtailed.
She said, well, let's have an exam. She examined me. Then we talked about what could be done. I asked her if she thought it would be a good option to have the surgery, have it removed, and she -- from what I recall, I felt like she said that we could get -- we probably wouldn't be able to get all the mesh, but we would be able to get the part that had sloughed off and become this -- the part that was very painful.
She drew a picture for me exactly what it looked like, you know, and it accordions down. That's the part she would try and take out.
Q. So if I heard you correctly, you made the initial request for surgery, is that correct, as an option?
A. No, no, no, no. I did not ask for surgery.
Q. Now, you said that Dr. Denman physically examined you. What did she do as far as a physical

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examination?
A. Well, it felt very similar to the one that Dr. Waugh did.
Q. Did she palpate inside your vagina?
A. Yes.
Q. Do you recall the specific area that she palpated?
A. Yes, I do.
Q. Can you tell me that?
A. The same one that Dr. Waugh palpated, the same one that Dr. Kuehl did. There's just one spot that hurts, and it's always the same place. She found it.
Q. Let's go to -- we're still on page MDR11, Bates label 11. I want to read the History of Present Illness. It says, "Becky is 59 years old, g6p6 with a history of a TVH for" -- I cannot pronounce this -- "menorrhagia and prolapse approximately nine years ago, 2009."
Am I reading that correctly?
A. Yes.
Q. "At which time she had an anterior and posterior repair for prolapse as well as an incontinence procedure."
Do you see that?
A. Yes.

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Q. "She did have mesh placed. The entire procedure was done vaginally. She did not have any issues immediately post-op, voided well and did not need a catheter."
Do you see that?
A. Yes.
Q. This record says you had no issues immediately post-op. That's true, right?
A. I don't recall.
Q. Then it says, "About a year after the procedure, she did have vaginal bleeding and went back to OR for a mesh revision."
Do you see that?
A. Yes. I don't know what OR is.
Q. Operating room.
A. Perfect. Okay.
Q. So about a year after you went in for a mesh revision. Is that also correct?
A. It was almost exactly a year. Yes.
Q. Then she goes on to say that after this she started to have dyspareunia which has never resolved.
Is that correct?
A. That's true. Yes.
Q. Now, going back to the page 11 where it talks about Plan, it says on No. 1, "Pain/Mesh - long discussion

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held regarding likely surgery that she had, reason for scarring, likelihood of decreasing pain with mesh removal."
Do you see that?
A. Uh-huh.
Q. Then at the end of this paragraph it says, "Discussed" -- last sentence says, "Discussed limited data guiding management; however, at this point she is interested in being more aggressive."
Do you see that?
A. Yes.
Q. Why did you want to be more aggressive?
A. I'd been living in pain for too long, living without sex for too long. I'm not getting any younger.
Q. Did you, having a lawsuit, have anything to do with your desire to be more aggressive?
A. No, no, no.
Q. Did Dr. Denman provide you with any alternatives to the mesh removal surgery?
A. Do nothing was one alternative. It wouldn't have resolved anything. I don't recall.
Q. Do you recall if Dr. Denman suggested trying pain medications first as an alternative?
A. I don't believe so.
Q. What about physical therapy as an alternative?

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A. No.
Q. What about did she provide trigger point injections as an alternative?
A. No.
Q. Did she say that you could do an estrogen regimen instead of surgery as an alternative?
A. No.
Q. Anything that you recall other than what you told me as an alternative to the mesh removal that Dr. Denman told you?
A. No.
Q. So it sounds like Dr. Denman didn't provide you with any alternatives other than to do nothing or to remove the mesh.
Is that correct?
MS. SCARCELLO: Object to the form of the question.
You can answer.
A. Can you repeat the question?
Q. BY MR. MANDELL: Dr. Denman provided you with no alternatives but to remove the mesh or do nothing; is that correct?
MS. SCARCELLO: Same objection.
You can answer.
A. I only remember the surgery one.

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Q. BY MR. MANDELL: Okay. And what was Dr. Denman's initial recommendation after performing the exam on you?
A. That it was very clear where the mesh was and that it was very painful there and removing it could possibly give me some relief.
Q. Did Dr. Denman provide you with any literature or patient brochures?
A. Not that I recall.
Q. It does say here on page 11 that -- if you look right above No. 2 under Plan, it says, "Handouts regarding pelvic floor website provided for additional resources for further information and support."
A. I do remember that. Yes. I do remember that.
Q. Did you review those?
A. No.
Q. So she offers it to you, but you never looked at them, right?
A. I took them home, and then I immediately -- I think I tried to look up one, and it was, like, forget it. Oh, man.
Q. You indicated that she drew a picture for you, right?
A. Yes.

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Q. Did she do any type of animation or videos?
A. No.
Q. Did she take any photographs?
A. After the surgery.
Q. Did anyone tell you your condition would resolve if you had your mesh removed?
A. No.
Q. Do you know if your implanting physician Dr. Kim and your explanting physician Dr. Denman coordinated, corresponded or communicated in any way about your care?
A. I have no idea.
Q. Now, it says here on page 11 -- tell me if you can see this, "Reviewed" -- this is under Plan. It's about three lines above the No. 2. It says, "Reviewed whether she's involved in lawsuit, she's responsible for obtaining directions as to how/if the mesh is to be preserved as evidence from her lawyers and to bring that with her to the hospital the DOS."
Do you see that?
A. Yes.
Q. Why did you tell Dr. Denman you were in a lawsuit?
A. She asked me.
Q. What did she ask you about the lawsuit?

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A. She just asked me if I -- after the whole meeting was over, I was up, had my coat on, my purse, heading out the door, and she said, are you in -- she said, are you in a lawsuit? She said, if you are, we'll need to get forms filled out so that we can preserve -- they'll want this mesh preserved.
Q. Any other discussion about the lawsuit with her?
A. No. No.
Q. Now, looking at the History of Present Illness on page 11, MDR11, we're looking at the second line there, it says, "At which time she had an anterior and posterior repair."
Did you report to Dr. Denman that you had a posterior repair?
A. I don't recall.
Q. We discussed earlier that Dr. Kim did not perform a posterior repair on you. Do you recall that?
A. I recall our discussion.
Q. But as far as your recollection, do you know one way or the other?
A. I don't understand the question.
Q. You recall our discussion. Do you know if a posterior repair was performed on you as you reported here to Dr. Denman?
MS. SCARCELLO: Object to the form of the

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question. I think it assumes facts not in evidence.
You can answer.
A. I don't know that I said that.
Q. BY MR. MANDELL: Now we're going to page 12. This is -- first sentence there -- actually, first line there, it looks like it's the third sentence that starts with "she was on vaginal."
Do you see that?
A. Yes.
Q. "She was on vaginal estrogen around the time of her surgeries but not long term." Does that -- is that true?
A. I believe so.
Q. It says, "She has not had pelvic floor PT," which I'll say represents physical therapy.
Was that true at the time?
A. That's true.
Q. "She is not on pain medication."
Was that true as well?
A. Yes.
Q. It indicates further down here on page 12 under the Genitourinary Current Symptoms, second-to-last one says, "Are you sexually active?" It says, "Yes."
Is that what you see there?
A. Yes.

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Q. Is it true that you were sexually active at this time?
A. Yes.
Q. As far as frequency, would it be the same as what you described to me in the last --
A. Yes.
Q. I'll finish my statement.
-- the last record with Dr. Waugh; is that right?
A. Yes.
Q. On page 13 under Gynecologic History, the last one there says, "Did you have any of the following?" It says, "Severe tearing/cutting or episiotomy, forceps delivery."
Do you see that?
A. I'm sorry. No. What page?
Q. Page 13 under Gynecologic History, the last one.
A. Yes.
Q. Do you recall what Dr. Denman had to say about that?
MS. SCARCELLO: Object to the form of the question.
You can answer.
A. No.
Q. BY MR. MANDELL: Do you recall having any discussion with Dr. Denman about severe tearing, cutting or

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episiotomy or the forceps delivery?
A. No.
Q. Dr. Denman put in her notes something called banding. Do you know what that is?
A. No.
Q. I take it you don't recall any discussion about that?
A. I'd have to know what banding was to answer that.
Q. Do you recall her using that word with you?
A. No.
Q. Now, it looks like on page 15 under Patient Counseling it says, "Please start the estrogen cream." It looks like she prescribes you estrogen cream to start on.
Is that right?
A. Yes.
Q. It says here, "In postmenopausal women, local estrogen use has been shown to improve tissue quality and decrease discomfort."
Do you see that?
A. Yes.
Q. Was that something you were also aware about from past providers like Ms. Kuehl and Dr. Kim?
A. Yes.
Q. From 2017 to currently, did you stop taking estrogen

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on your own accord at any point?
A. No. I used the prescriptions and stopped when they were done.
Q. It's your understanding that you followed whatever doctors' instructions it was as far as using the estrogen cream to completeness?
A. Yes.
Q. It looks like the next step here was to schedule your explant procedure; is that right?
A. I believe so.
Q. Did you ever seek a second opinion regarding whether an explant should be performed on you?
A. I kind of felt like Dr. Denman was the second one since I'd already seen Dr. Waugh.
Q. Dr. Waugh never indicated an explant; is that correct?
A. I'm not sure what she indicated.
Q. That's why I'm asking you, as far as the second opinion for the explant, the removal of the mesh, did you see any other doctors for a second opinion?
A. I did not.
Q. Why not?
A. Because I believed that Dr. Denman was actually the second one because Lindsey Waugh had sent me to her because that's what she does. So I really believed

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that that was -- it felt like my second one.
Q. Now we'll go to MDR8. This is on October 26, 2018, and this is -- it looks like your pre-op appointment.
Does that look correct to you?
A. It sounds right.
Q. This is again with Dr. Denman, correct?
A. Yes.
Q. It says here under History of Present Illness -- do you see that section?
A. Yes.
Q. Second sentence starts with, "She has a history of an anterior mesh placed for prolapse that has subsequently caused her a great deal of pain."
Do you see that?
A. Yes.
Q. Did I read that correctly?
A. Yes.
Q. Did you tell Dr. Denman that you had a great deal of pain?
A. Yes. Over a period of time I would say the dull pain leads to a great deal of pain.
Q. Then the next sentence says, "She has tried to manage this. However, it is not improving and she would like the mesh removed to allow for increased

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vaginal mobility and the potential for improvement with physical therapy."
Did I read that correctly?
A. "For increased vaginal mobility." Obviously you read it correctly.
Q. Did you tell Dr. Denman that you tried to manage this pain that you -- strike that.
It indicates here that you had tried to manage this pain. Is that something you told Dr. Denman?
A. Absolutely.
Q. So that was true, correct?
A. Yes.
Q. How did you try to manage the pain?
A. Through eating well, trying to exercise, trying not to think about it.
Q. When you say trying to exercise, what types of exercise did you do to manage the pain?
A. I tried yoga. I tried Zumba. I've tried just stretching. All kinds of things. Walking. Mostly walking because that's really all I can manage.
Q. When were you trying these things to manage the pain? I presume it was sometime between when you had your revision to when you saw Dr. Denman?
A. Since the revision I've had issues with the pain.
Q. But you mention that you tried to manage it with

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Zumba, yoga, eating well, right? Did I say that correctly?
A. Yes.
Q. What was the result of trying to manage it with those activities?
A. It didn't work. The pain was still there during sex, just a constant friend that hung out with me.
Q. Now, it says here under Plan, "PARQ," P-A-R-Q, held with patient. All risk and benefits discussed and all questions answered."
Do you see that?
A. Yes, I do.
Q. I'll represent to you that PARQ indicates the provider has explained the procedures, which stands for P, viable alternatives for A, material risks for R, and has asked if the patient has questions for Q.
A. Okay.
Q. Is it true that Dr. Denman held this conference with you on 10-26-2018?
A. Yes, it is.
Q. What risks and benefits were discussed?
A. One of the risks I remember was that my bladder could be punctured, which would be an issue but could be fixed. The benefit would be that the pain may be reduced.

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Q. Did she discuss with you that your incontinence or cystocele or organ prolapse could recur?
A. No.
Q. Did she discuss with you that you could have -- one of the risks would be further pelvic and vaginal pain?
A. I don't recall.
Q. Did she discuss that one of the risks of the surgery was pain with intercourse?
A. No. I don't recall.
Q. Did she discuss that one of the risks of surgery was vaginal scarring?
A. I don't recall.
Q. Did she discuss that one of the risks of the surgery was failure of the surgery?
A. Yes.
Q. So you recall that, but you don't recall if she discussed any of the other items I mentioned?
A. Those seem very specific, and I guess the failure adds up to all of those.
Q. Do you recall her discussing any other risks that --
A. No, I don't.
Q. It's true that any questions you had at the time were answered?
A. Yes.

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Q. And you understood the risks that Dr. Denman told you and consented to the surgery; is that correct?
A. Yes.
Q. Would you defer to Dr. Denman as to what she warned you about as far as the risks of this procedure?
A. Can you --
Q. Yes. I'll try to say it in more concise terms.
Would you defer to what Dr. Denman says as far as what she warned you about the risks of this procedure?
A. Yes.
Q. Now, do you know how long your discussion with Dr. Denman lasted?
A. No, I don't.
Q. Prior to surgery, did you do any research of your own on the course of treatment that Dr. Denman outlined?
A. Not that I recall.
Q. Again here on page -- under Plan, the last sentence there says -- this is page 8, Bates labeled 8, "She will bring whatever documents and travel container is required by her layer' -- I think she meant to say lawyer -- "for the mesh lawsuit she is currently in."
Do you see that?

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A. Uh-huh.
MS. SCARCELLO: Is that a "yes"?
A. Yes.
Q. BY MR. MANDELL: What discussion did you have with Dr. Denman at this appointment regarding your lawsuit?
A. It's the same point, isn't it?
Q. This is actually October 26.
A. I do recall. The surgery had to be done at a different hospital because of my insurance. She only does that one day a month. So that was going to be a problem with -- she felt like it could be a problem with the lab and collecting the specimen, so she suggested that I bring the document or the container, whatever it's going to be in. It did not work out like that, but that's -- she felt like it wouldn't get lost.
Q. As far as these documents that she's mentioning, can you tell me -- can you describe to me what these documents were?
A. She didn't know what I would need. She just said -- I don't know what it ended up to be because I wasn't -- didn't have them.
Q. Did you ever bring her documents from your lawyers?
A. Absolutely not.

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Q. Were your lawyers present for any appointments with Dr. Denman?
A. No.
Q. Now, you signed an informed consent form for the surgery, right?
A. Yes.
Q. I'll just introduce this as an exhibit real quick. This will be Exhibit 5.
(Marked Deposition Exhibit No. 5.)
Q. BY MR. MANDELL: I want to confirm that's your signature on this page?
A. Yes.
Q. It says here that the -- you'll see on this document it says, "The procedures, benefits, material risks and reasonable alternatives were explained to me. All of the questions about the procedures, benefits, material risks and reasonable alternatives were answered to my satisfaction."
Do you see that part?
A. Yes.
Q. Again, as we discussed, Dr. Denman went over the risks as noted here as well, and you consented, right?
A. Yes.
Q. So you gave permission for this procedure to be done

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on you, right?
A. Yes.
Q. As indicated on this consent form, you were aware that there was no guarantee that the surgery would resolve your issues of pelvic or vaginal pain or pain with intercourse; is that correct?
A. Yes.
Q. Now, tell me about your explant procedure. Do you know -- this occurred on November 16, 2018?
A. Yes.
Q. Do you know what specifically Dr. Denman did?
A. I believe she extracted five pieces of the mesh. She showed me a picture of them because I asked her to. She said that they came very close to the bladder, but she left pieces in that she couldn't retrieve.
Q. Did Dr. Denman ever explain to you that she was going to leave in certain mesh that wasn't causing you any issues and remove the ones that she believed were causing you issues?
A. No.
Q. Did Dr. Denman ever tell you she was removing mesh from the Avaulta product versus the Align product?
A. No.
Q. To your understanding, do you still have mesh in

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you?
A. I believe so.
Q. Do you know what mesh it is, whether the Avaulta or the Align?
A. I'm sorry. No.
Q. Do you know what happened with the mesh that Dr. Denman took out?
A. It was collected and I believe provided to my lawyers.
Q. Did Dr. Denman or any healthcare provider have anything to say about the mesh that was removed?
A. No.
Q. Let's talk about your recovery from the explant procedure. Did you speak to Dr. Denman immediately following the explant?
A. Yes.
Q. What did -- what was that conversation?
A. She told me that she got five pieces. She showed them to me on her phone because that's what I asked her to do. She said there was still pieces in. She didn't -- she explained that my bladder was still intact and that the surgery went well.
Q. So no complications; is that correct?
A. Not as far as I know.
Q. You were given discharge instructions, right?

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A. Yes.
Q. Did you follow those instructions?
A. Yes.
Q. Now I want to go to your post-op appointments with Dr. Denman, which will be page MDR Bates label 32.
A. It's a lot of pages.
Q. Here it says it's December 3, 2018, office first, first post-op visit.
Do you see that?
A. Yes.
Q. I'm correct in saying this is your first post-op visit with Dr. Denman?
A. Uh-huh. It's like a week after, I believe.
Q. Under the Comments, do you see this section under No. 6, Comments?
A. Yes.
Q. It says, "No urinary incontinence, minimal pain, having vaginal drainage."
A. Yes.
Q. Did I read that correctly?
A. Uh-huh. Yes.
Q. That's true?
A. Can I add a little addendum to that?
Q. Whatever you'd like.
A. Later I found out that the medication -- the numbing

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medication they give you is pretty strong because a week after then the pain returned.
Q. What was this numbing medication? Do you know the name of it?
A. No. It's the surgery medication. I have no idea.
Q. This was --
A. On the 16th.
Q. This post-op is about two weeks after your surgery, maybe even a little more, actually, three weeks.
A. Uh-huh.
Q. You wouldn't have been on numbing medication still then, would you?
A. I don't think so, but I'm telling you the pain increased after this visit. You'll probably see it on another one.
Q. Let's go to page 33. This is still the same visit. Under Exam it says, "Other." It says, "Nontender to palpation."
Do you see that?
A. Yes.
Q. Do you know what it is to palpate?
A. Yes.
Q. Was that true that it was nontender at that time?
A. I trust that her notes are correct.
Q. Now your next visit I have, which is going to be on

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MDR Bates label 30, this is January 2, 2019, so this is about a month after your last -- the last visit we were just talking about.
A. Okay.
Q. You'll see here it's January 2, 2019, office visit, second post-op visit, correct?
A. Okay.
Q. That's with Dr. Denman as well, right?
A. Yes.
Q. It says here under No. 1, "Pain controlled: Yes."
Do you see that?
A. Yes.
Q. Then under No. 4 it says, "Problems with voiding: No."
Do you see that?
A. Yes.
Q. "Problems with leaking urine: No."
Do you see that?
A. Yes.
Q. Just focusing on those last two that I said, you were not having any stress urinary incontinence issues, right?
A. No.
Q. You currently don't have any stress urinary incontinence issues, right?

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A. No, I don't.
Q. That's been cured since 2008 when you had the implant?
A. Yes.
Q. The cystocele that you had the Avaulta for, that remains resolved since the 2008 implant as well, right?
A. Okay. I don't know what you are talking about. Go ahead.
Q. If you don't know, I don't want you to guess.
As far as -- here it says, "Pain controlled: Yes." I don't see any comments here about having any additional pain.
A. It also says there's no vaginal bleeding, and that is -- you know, there's -- that has started or was after that because I still have it.
Q. I think -- you can correct me if I'm wrong, but it says on the next page, "Plan: Okay for intercourse after two weeks." At this point you had not had intercourse.
A. Okay.
Q. So the vaginal bleeding, that's a correct statement that you have no vaginal bleeding?
A. Okay. Great.
Q. It's also a correct statement that your pain was

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controlled as stated here, right, at this time?
A. I believe so.
Q. Again, Dr. Denman examines you. If you go to page 31, it says, "Vaginal exam: Nontender, discharge c/w postoperative change" -- "consistent with postoperative changes."
Do you see that under Exam?
A. There. Thank you.
Q. Did I read that correctly?
A. Yes.
Q. What did she -- as far as this vaginal exam, what did she do?
A. I don't -- she did a vaginal exam, looked inside, touched. You know, she could see there was a part that wasn't healing, this tissue.
Q. It says -- it looks like here under Instructions on the same page there's an instruction to continue your use of estrogen; is that correct?
A. Yes.
Q. Did you do that?
A. Yes, I did.
Q. It also indicates here under Plan on Bates label 31 that follow-up is needed as she is going on a two-month trip.
A. Yes.

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Q. Did you go on this two-month trip?
A. Yes, I did.
Q. Where did you go to?
A. I drove to Texas.
Q. What did you do during this trip?
A. Camped, bird watched, sat in the car a lot.
Q. What sort of camping activities did you do?
A. Bird watching, tried to hike. Didn't work that well.
Q. What year was this?
A. Just this year.
Q. Do you know what month?
A. January, February.
MS. SCARCELLO: Can we take a break?
MR. MANDELL: Yes. Let's take a break.
(Recess.)
Q. BY MR. MANDELL: We're back on the record. We're discussing this two-month follow-up after your explant procedure, right?
A. Yes.
Q. There's no indication here about you having any pain; is that correct?
A. During the two months?
Q. At this two-month follow-up, you did not report having any pain; is that correct?

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A. Yes. That's what it looks like. I don't recall no pain. I think there was much less pain than what I -- I kind of expected it to be no pain.
Q. But you indeed even requested follow-up to see if you can go on a two-month trip at this point?
A. Absolutely.
Q. So you were feeling better, right?
A. I wanted to feel better.
Q. Then it says you were okay for intercourse after two weeks. After these two weeks, is that when you believe you first attempted that?
A. I don't know where we're at here. How long is this after the surgery?
Q. This is two months after. That would be, like you said, I think ten weeks after surgery.
A. So this is -- so it was two weeks after we started our trip. That would be, like, the middle of January.
Q. That's when you first attempted to have --
A. I'm just trying to make sure I have this.
Q. This trip that you went on, who went on this trip to Texas with you?
A. My husband and I and our dog. We have a truck, and we have a travel trailer.
Q. Did you guys take any photos on this trip?

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A. No. We were bird watching.
Q. Have you taken any other vacations since your 2018 explant?
A. We -- yes. We drove to -- we went camping again. We went travel trailering to Burns, Oregon, Malheur Wildlife Refuge.
Q. Was that for bird watching as well?
A. It is.
Q. Are you a big fan of bird watching?
A. It's a way to get outside. I can't do a whole lot, but I can watch birds.
Q. Did you do any hiking on this trip?
A. Not at all.
Q. But you did attempt to do some hiking on your Texas trip; is that correct?
A. But was unable to.
Q. What was the reason why you were unable to?
A. I didn't have the energy. It hurt. The pain was just too much.
Q. When you say it hurt, can you tell me where?
A. My vaginal area hurt.
Q. Pelvic area?
A. Pelvic.
Q. Can you be more precise as to where in the pelvic area?

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A. The same place it always hurt.
Q. When you say the same place it always hurt, are you referring since the 2008 surgery place?
A. Yes. Well, not since the 2008. It didn't hurt until way after that, until after the revision.
Q. When was the last time you saw Dr. Denman? Was it --
A. It was June 1.
Q. So you did have another visit after this January --
A. Uh-huh.
Q. Let me ask you this. What did Dr. Denman tell you about your recovery from the explant procedure at this appointment in January 2019? Do you recall?
A. She -- I recall that I wasn't healed yet.
Q. Was her -- then the next time you saw her was June --
A. June 1.
Q. -- 2019. What did you see her for then?
A. Because I was bleeding still and wanted to know what that was all about.
Q. What did Dr. Denman tell you at this visit?
A. I still wasn't healed. I had an area in my vaginal wall that is not healed which -- so she says that could be causing the pain. She gave me some medicine, put some medicine in. Then she said I may

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have to have another surgery.
Q. The vaginal wall not healed that you are talking to me about, did she tell you when she thinks that would heal?
Let me strike that question?
Did Dr. Denman say that your vaginal wall that hasn't healed yet, will eventually heal?
A. She's hoping it will. But if not, she gave me an alternative what we would do.
Q. What was that alternative?
A. To do surgery to take the piece out that is not healing, I assume somehow scar that over so that it's -- so it's not bleeding anymore. I don't know.
Q. The bleeding issue, that's related to when you have sex; is that correct?
A. Yes. But I have breakout bleeding as well. Like I said, it's from this part that's not healed.
Q. Can you tell me location-wise where this part is that's not healed?
A. I haven't reached it. I'm sorry.
Q. Did Dr. Denman provide you with a prognosis?
A. I'm not sure what you are asking.
Q. What did Dr. Denman -- does Dr. Denman say anything about how your future looks?
A. She said that my vaginal tissues look great.

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Q. Did Dr. Denman say anything about -- in your last visit in June, did you discuss with Dr. Denman the dull vaginal pain that you claim you still have and your pain with intercourse?
A. Yes.
Q. What did Dr. Denman have to say about those two things?
A. She said we'll have to wait until it's healed up to see if that is part of the issue or what we can do next.
Q. Do you have -- do you currently have any doctor appointments scheduled?
A. No.
Q. Other than this surgery that you told me Dr. Denman brought up regarding the vaginal wall that hasn't healed yet, have you been recommended any other future surgery?
A. No.
Q. You would agree with me, though, that since your explant your injuries of pelvic pain and vaginal pain as well as pain with sex have improved to some level, correct?
A. At some level.
Q. In your last deposition you covered -- we covered the hobbies and activities you could no longer do

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following the mesh implant. To repeat those, those were yoga, Zumba, aerobics, long hiking and kayaking.
Do you recall saying that?
A. I probably said that.
Q. Did that remain true from the time of your deposition in 2017 to your explant in 2018?
A. Yes.
Q. Were there any additional activities that you could no longer do in that time frame?
A. Not that I can think of.
Q. Since your explant, have you attempted to do any of these activities? I know we discussed the hiking.
A. Yes.
Q. What else have you attempted?
A. I tried bike riding. I tried the hiking. Kayaking I don't do anymore just because I'm worried about -- you know, I'm just worried. You know, I'm scared to do things. I did yoga at home off of my computer, you know, following somebody. Those are the ones I haven't been successful with that I've attempted.
Q. So my understanding is you've attempted all these, but they still for you were not something that you continue doing?
A. Right. Either it was painful or it just was I

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couldn't keep it up, too tiring.
Q. Any of these activities -- did you not do any of these activities due to any of your other conditions such as your carpal tunnel syndrome or depression?
A. They were not the reasons.
Q. Has any healthcare provider said you cannot perform these activities of yoga, kayaking, riding a bike, long hikes?
A. No.
Q. Has any healthcare provider told you to limit those activities that I just mentioned?
A. No.
Q. Are there any additional activities or household chores you cannot perform since you had the explant?
A. Well, there's a lot of things I don't do because of that. I don't mow the lawn. I don't chop wood. When we go camping, I don't do any of the physical activity. I don't set up the trailer. I don't break it down. I do basically the cooking. That's all.
Q. Did you do those things from 2017 to 2018?
A. No. Before that I did.
Q. Just so I understand your current condition with sex just a little better, the pain with sex, can you give me currently your best description of how it

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feels and where it's located?
A. It's already written in here.
Q. So it's remained the same?
A. It's the same.
Q. As your testimony from 2017?
A. Yes.
Q. And I believe you testified to this before, but I'm asking you again. It has diminished in its pain level, though; is that correct?
A. It has. But it's increased in bleeding.
Q. So the -- can you give me a scale on one to ten to where the pain level is now after the explant when you have sex?
A. Six, seven.
Q. Where was it just before the explant, so from 2017 to 2018?
A. Eight or nine.
Q. We're almost done here. Have you ever received any information directly from Bard regarding the Align or Avaulta?
A. No.
Q. When you had your implant for those products, you relied on the information -- when you had those products implanted in you, did you rely entirely on the information that Dr. Kim gave you?

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A. Yes.
MS. SCARCELLO: Object to the form of the question. It was -- could have been asked in 2017 and direct you not to answer.
(Instruction not to answer.)
Q. BY MR. MANDELL: You already answered as well, though.
Do you have any type of contract with Bard?
A. No.
Q. Since 2017, have you posted anything related to this lawsuit, the mesh or Bard on any social media platform?
A. No.
Q. Do you recall ever at any point reading any warranty language related to mesh implanted in you in 2008?
A. No.
Q. Other than your lawyers with whom you've discussed this lawsuit, and we'll focus on the time from 2017 to now, has anyone other than them told you that Bard did anything wrong?
A. No.
Q. Has anyone other than your attorneys told you that Bard was negligent?
A. No.
Q. Has anyone other than your attorneys told you that

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Bard, Avaulta or Align devices implanted into you were defective?
A. No.
Q. Has anyone other than your attorneys told you that Bard did not give adequate warnings to your physicians?
A. No.
Q. Has anyone other than your attorneys ever told you that Bard did not give adequate instructions to your physicians?
A. (Shakes head.)
Q. That was a "no"?
A. I'm sorry. No.
Q. Have you shared with me now all of your complaints about Bard's Align and Avaulta products since 2017 to the present?
A. I believe so.
Q. All right. Thank you for your time, Ms. Smith.
MS. SCARCELLO: I have a few follow-ups.

EXAMINATION
BY MS. SCARCELLO:
Q. Earlier today you testified that when deciding to start you on Wellbutrin that Nikki Kuehl considered your ability to be physically active.

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Do you recall that?
A. Yes.
Q. And your ability to be active is substantially diminished due to your pelvic pain, correct?
A. Yes.
MR. MANDELL: Objection; leading.
Q. BY MS. SCARCELLO: Walking is your primary source of exercise, right?
MR. MANDELL: Same objection.
A. Yes.
Q. BY MS. SCARCELLO: Has your diminished capacity for physical activity due to pelvic pain caused you to experience feelings of sadness?
MR. MANDELL: Same objection.
A. Yes.
Q. BY MS. SCARCELLO: Does it make you feel despondent?
A. Yes.
MR. MANDELL: Same objection.
Q. BY MS. SCARCELLO: Does the constant pain cause you to feel fatigued at times?
A. Yes.
MR. MANDELL: Same objections.
Q. BY MS. SCARCELLO: Is it fair to say that the pelvic pain you experience with physical activity and your resulting inactivity has actually contributed to

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your depressive symptoms?
MR. MANDELL: Same objection.
A. Absolutely.
MS. SCARCELLO: Nothing further.
MR. MANDELL: I'll have some follow-ups on that.

FURTHER EXAMINATION

BY MR. MANDELL:
Q. Ms. Smith, you were diagnosed with depression prior to your implant, correct?
A. Yes.
Q. That's something you've been dealing with for quite a long time, correct?
MS. SCARCELLO: I'll object to the form of the question to the extent that it calls for testimony previous to 2017 and direct her not to answer.
(Instruction not to answer.)
Q. BY MR. MANDELL: Are you claiming that the mesh is related in any way to your depression?
A. Yes.
MR. MANDELL: If she's going to claim that, then it's open. This is a new injury that's changed since her last testimony.
MS. SCARCELLO: I think the emotional injuries are documented in here with respect to the -- okay.

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It's our position they are. I'll direct her not to answer anything previous to 2017. Her ability to be intimate with her husband -- he has brought a loss of consortium claim, so I believe that the emotional injuries in this case have been pled and discussed in the discovery prior to the April 2017 deposition.
MR. MANDELL: I'm going to respectfully disagree. If we aren't able to ask some of these questions, we may have to keep this deposition open. I'll let you decide if you want to do that. I will try to frame some of these questions as best I can from the 2017 time frame.
MS. SCARCELLO: To be clear, my line of questioning was related to the Wellbutrin prescription specifically, which happened in -- she said she's been on that for about a year, so probably sometime in 2018. That's what my questions were directed to.
Q. BY MR. MANDELL: Your Wellbutrin prescription, that was for depression, right?
A. Yes.
Q. You went to Nikki Kuehl for that prescription, correct?
A. Yes.
Q. The reason was because your prior prescription of

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Lexapro was not fully treating your depression at the time; is that right?
A. The reason I went to her is because I was still feeling -- actually feeling very unwell in my depression. I couldn't exercise, which is -- the year before when we discussed it, that was the biggest thing I could do for my depression. We talked about another option, which would be to use a different medication.
Since a whole year had passed, I was still very unable to do the exercise, which was contributing and I believe contributes to my depression. So the Wellbutrin was added because I couldn't exercise adequately.
Q. Has any physician ever told you that your increase in depression was related to your mesh?
A. No.
Q. From 2017 until before you had this Wellbutrin prescription, you were suffering from depression on a daily basis; is that right?
A. That's how it works. Yes.
Q. Have you sought treatment from anyone else other than nurse practitioner Kuehl for depression since 2017?
A. No.

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Q. One of the records that we discussed earlier, and I can bring it up if necessary, mentioned your husband had a pulmonary embolism.
Do you recall that?
A. I recall his pulmonary embolism. Absolutely.
Q. That record indicated that it was giving you a lot of stress at the time.
Does that sound accurate?
A. Yes. It's my husband.
Q. So this could have contributed to your depression at the time as well, correct?
A. I don't know.
Q. So you don't know what exactly could have contributed to your depression when you were prescribed Wellbutrin in 2018; is that right?
A. I know I was prescribed Wellbutrin as an alternative for my inactivity.
Q. You don't know what other causes -- let me strike that.
Were you told by any healthcare provider of any specific causes other than -- strike that.
Did nurse practitioner Kuehl say she was -- specifically say she was prescribing the Wellbutrin due to your inactivity?
A. It's the impression I got.

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Q. Did nurse practitioner Kuehl tell you what was the cause for why you needed Wellbutrin?
A. Because my original medication wasn't working well enough.
Q. If I get this straight, the only discussion that was discussed was that your prior medicine wasn't working well enough, but there was no discussion as to why it wasn't working?
A. The year before when I went to her, we discussed my Lexapro and how it was working, and we discussed how we could resolve those issues staying on the Lexapro by using -- exercise would be great, losing weight would be great, and so a whole year of that not working, by the time I went to see her again, we discussed -- and she had seen my vaginal discomfort. She knew about that. That's when she gave me Wellbutrin.
Q. Again, she never said that the Wellbutrin was being prescribed because of the mesh; is that correct?
A. Yes. That's correct.
Q. How are you dealing with your depression today?
A. The Wellbutrin seems to be working well enough. I have to be very careful to take it very carefully.
Q. So since --
A. Don't miss any.

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Q. Sorry for cutting you off.
Since you've been prescribed the Wellbutrin, you notice an improvement in your depression, is that correct, your symptoms?
A. Uh-huh.
Q. Is that a "yes"?
A. Yes.
Q. Do you have any -- is there any future decision to go to a doctor for additional treatment of depression at this point?
A. It's just -- every time I go for my well woman exam, it's part of the discussion.
Q. Basically since --
A. August.
Q. -- August of 2018 there's been nothing to complain about further as far as the depression; is that right?
A. Correct.
Q. I think that's all I have. Thank you.
MS. SCARCELLO: I don't have any more questions. Let's go off the record.
MR. MANDELL: Off the record.
(Discussion off the record.)
MR. MANDELL: Ms. Smith has decided to waive reviewing the record and making any changes. Thank

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you.
(DEPOSITION ADJOURNED at 4:52 p.m.)
* * *

CERTIFICATE

I, Joyce Imrie, Oregon CSR No. 94-0293, Washington CSR No. 2792, do hereby certify that BECKY R. SMITH personally appeared before me at the time and place mentioned in the caption herein; that the witness was by me first duly sworn on oath and examined upon oral interrogatories propounded by counsel; that said examination, together with the testimony of said witness, was taken down by me in stenotype and thereafter reduced to typewriting; and that the foregoing transcript, pages 84 to 201, both inclusive, constitutes a full, true and accurate record of said examination of and testimony given by said witness, and of all other proceedings had during the taking of said deposition and of the whole thereof, to the best of my ability.

Witness my hand at Portland, Oregon, this ^ day of June, 2019.

_____

JOYCE IMRIE
OCSR No. 94-0293, Expires 9-30-2020
WCSR No. 2792, Expires 8-6-2019

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EXHIBIT 4

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

Medical Devices

FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence

For updated information about Surgical Mesh for Pelvic Organ Prolapse, see: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse [1], released July 13, 2011.

Issued: October 20, 2008

Dear Healthcare Practitioner:

This is to alert you to complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI). Although rare, these complications can have serious consequences. Following is information regarding the adverse events that have been reported to the FDA and recommendations to reduce the risks.

Nature of the Problem

Over the past three years, FDA has received over 1,000 reports from nine surgical mesh manufacturers of complications that were associated with surgical mesh devices used to repair POP and SUI. These mesh devices are usually placed transvaginally utilizing tools for minimally invasive placement.

The most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. There were also reports of bowel, bladder, and blood vessel perforation during insertion. In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia.

Treatment of the various types of complications included additional surgical procedures (some of them to remove the mesh), IV therapy, blood transfusions, and drainage of hematomas or abscesses.

Specific characteristics of patients at increased risk for complications have not been determined. Contributing factors may include the overall health of the patient, the mesh material, the size and shape of the mesh, the surgical technique used, concomitant procedures undertaken (e.g. hysterectomy), and possibly estrogen status.

Recommendations

Physicians should:

- Obtain specialized training for each mesh placement technique, and be aware of its risks.
- Be vigilant for potential adverse events from the mesh, especially erosion and infection.
- Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.
- Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
- Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall (in POP repair).
- Provide patients with a written copy of the patient labeling from the surgical mesh manufacturer, if available.

Additional patient information [2] can be found on the following FDA Consumer website.

Reporting Adverse Events to FDA

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to the use of surgical mesh, you should follow the reporting procedure established by your facility.

We also encourage you to report adverse events related to surgical mesh that do not meet the requirements for mandatory reporting. You can report directly to MedWatch, the FDA Safety Information and Adverse Event Reporting program online [3], by phone at 1-800-FDA-1088, or obtain the fillable form online [4], print it out and fax to 1-800-FDA-0178 or mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787.

Getting More Information

If you have questions about this Notification, please contact FDA's Office of Surveillance and Biometrics by e-mail at phann@fda.hhs.gov or by phone at 301-796-6640.

FDA Medical Device Public Health Notifications [5] are available on the Internet. You can also be notified through email each time a new Public Health Notification is added to our web page. To subscribe, visit: http://service.govdelivery.com/service/subscribe.html?code=USFDA_39 [6].

Sincerely,

Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration

Links on this page:

1. /MedicalDevices/Safety/AlertsandNotices/ucm262435.htm
2. /MedicalDevices/Safety/AlertsandNotices/ucm142636.htm
3. /Safety/MedWatch/default.htm
4. /Safety/MedWatch/HowToReport/DownloadForms/default.htm

5. /MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/default.htm
6. http://service.govdelivery.com/service/subscribe.html?code=USFDA_39

EXHIBIT 5

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

Medical Devices

FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse

Date Issued: July 13, 2011

Audience:

- Health care providers who implant surgical mesh to repair pelvic organ prolapse and/or stress urinary incontinence
- Health care providers involved in the care of patients with surgical mesh implanted to repair pelvic organ prolapse and/or stress urinary incontinence
- Patients who are considering or have received a surgical mesh implant to repair pelvic organ prolapse and/or stress urinary incontinence

Medical Specialties: gynecology, urogynecology, urology, general surgery, internal medicine, family practice, emergency medicine

Device:
Surgical mesh is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material or absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence.

Background:
Pelvic Organ Prolapse
Pelvic organ prolapse (POP) occurs when the tissues that hold the pelvic organs in place become weak or stretched. Thirty to fifty percent of women may experience POP in their lifetime with 2 percent developing symptoms. When POP happens, the organs bulge (prolapse) into the vagina and sometimes prolapse past the vaginal opening. More than one pelvic organ can prolapse at the same time. Organs that can be involved in POP include the bladder, the uterus, the rectum, the top of the vagina (vaginal apex) after a hysterectomy, and the bowel.

Stress Urinary Incontinence
Stress urinary incontinence (SUI) is a leakage of urine during moments of physical activity, such as coughing, sneezing, laughing, or exercise.

Purpose:
On Oct. 20, 2008, the FDA issued a Public Health Notification and Additional Patient Information on serious complications associated with surgical mesh placed through the vagina (transvaginal placement) to treat POP and SUI.

Based on an updated analysis of adverse events reported to the FDA and complications described in the scientific literature, the FDA identified surgical mesh for transvaginal repair of POP as an area of continuing serious concern.

The FDA is issuing this update to inform you that serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**. This is a change from what the FDA previously reported on Oct. 20, 2008. Furthermore, it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk. This Safety Communication provides updated recommendations for health care providers and patients and updates the FDA's activities involving surgical mesh for the transvaginal repair of POP.

The FDA continues to evaluate the effects of using surgical mesh to repair SUI and will communicate these findings at a later date.

For detailed information, please see: Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse. [1]

Summary of Problem and Scope:
In the Oct. 20, 2008 FDA Public Health Notification, the number of adverse events reported to the FDA for surgical mesh devices used to repair POP and SUI for the previous 3-year period (2005 – 2007) was "over 1,000." Since then, from Jan. 01, 2008 through Dec. 31, 2010, the FDA received 2,874 additional reports of complications associated with surgical mesh devices used to repair POP and SUI, with 1,503 reports associated with POP repairs and 1,371 associated with SUI repairs. Although it is common for adverse event reporting to increase following an FDA safety communication, we are concerned that the number of adverse event reports remains high.

From 2008 – 2010, the most frequent complications reported to the FDA for surgical mesh devices for POP repair include mesh erosion through the vagina (also called exposure, extrusion or protrusion), pain, infection, bleeding, pain during sexual intercourse (dyspareunia), organ perforation, and urinary problems. There were also reports of recurrent prolapse, neuro-muscular problems, vaginal scarring/shrinkage, and emotional problems. Many of these complications require additional intervention, including medical or surgical treatment and hospitalization.

In order to better understand the use of surgical mesh for POP and SUI, the FDA conducted a systematic review of the published scientific literature from 1996 – 2011 to evaluate its safety and effectiveness. The review showed that transvaginal POP repair with mesh does not improve symptomatic results or quality of life over traditional non-mesh repair. The FDA continues to evaluate the literature for SUI surgeries using surgical mesh and will report about that usage at a later date.

In particular, the literature review revealed that:

- Mesh used in transvaginal POP repair introduces risks not present in traditional non-mesh surgery for POP repair.
- Mesh placed abdominally for POP repair appears to result in lower rates of mesh complications compared to transvaginal POP surgery with mesh.
- There is no evidence that transvaginal repair to support the top of the vagina (apical repair) or the back wall of the vagina (posterior repair) with mesh provides any added benefit compared to traditional surgery without mesh.
- While transvaginal surgical repair to correct weakened tissue between the bladder and vagina (anterior repair) with mesh augmentation may provide an anatomic benefit compared to traditional POP repair without mesh, this anatomic benefit may not result in better symptomatic results.

The FDA's literature review found that *erosion* of mesh through the vagina is the *most common and consistently reported mesh-related complication* from transvaginal POP surgeries using mesh. Mesh erosion can require multiple surgeries to repair and can be debilitating for some women. In some cases, even multiple surgeries will not resolve the complication.

Mesh contraction (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA since the Oct. 20, 2008 *FDA Public Health Notification*. Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain.

Both mesh erosion and mesh contraction may lead to severe pelvic pain, painful sexual intercourse or an inability to engage in sexual intercourse. Also, men may experience irritation and pain to the penis during sexual intercourse when the mesh is exposed in mesh erosion.

The complications associated with the use of surgical mesh for POP repair have not been linked to a single brand of mesh.

Recommendations for Health Care Providers:

As stated in the Oct. 20, 2008 Public Health Notification, the FDA continues to recommend that health care providers should:

- Obtain specialized training for each mesh placement technique, and be aware of the risks of surgical mesh.
- Be vigilant for potential adverse events from the mesh, especially erosion and infection.
- Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.
- Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
- Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall in POP repair using surgical mesh.
- Provide patients with a copy of the patient labeling from the surgical mesh manufacturer if available.

In addition, the FDA also recommends that health care providers:

- Recognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications.
- Choose mesh surgery only after weighing the risks and benefits of surgery with mesh versus all surgical and non-surgical alternatives.
- Consider these factors before placing surgical mesh:
    - Surgical mesh is a permanent implant that may make future surgical repair more challenging.
    - A mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications.
    - Removal of mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible and may not result in complete resolution of complications, including pain.
    - Mesh placed abdominally for POP repair may result in lower rates of mesh complications compared to transvaginal POP surgery with mesh.
- Inform the patient about the benefits and risks of non-surgical options, non-mesh surgery, surgical mesh placed abdominally and the likely success of these alternatives compared to transvaginal surgery with mesh.
- Notify the patient if mesh will be used in her POP surgery and provide the patient with information about the specific product used.
- Ensure that the patient understands the postoperative risks and complications of mesh surgery as well as limited long-term outcomes data.

Recommendations for Patients:

Before Surgery

Be aware of the risks associated with surgical mesh for transvaginal repair of POP. Know that having a mesh surgery may put you at risk for needing additional surgery due to mesh-related complications. In a small number of patients, repeat surgery may not resolve complications.

Ask your surgeon about all POP treatment options, including surgical repair with or without mesh and non-surgical options, and understand why your surgeon may be recommending treatment of POP with mesh.

In addition, ask your surgeon these questions before you agree to have surgery in which surgical mesh will be used:

- Are you planning to use mesh in my surgery?
- Why do you think I am a good candidate for surgical mesh?
- Why is surgical mesh being chosen for my repair?
- What are the alternatives to transvaginal surgical mesh repair for POP, including non-surgical options?
- What are the pros and cons of using surgical mesh in my particular case? How likely is it that my repair could be successfully performed without using surgical mesh?
- Will my partner be able to feel the surgical mesh during sexual intercourse? What if the surgical mesh erodes through my vaginal wall?
- If surgical mesh is to be used, how often have you implanted this particular product? What results have your other patients had with this product?
- What can I expect to feel after surgery and for how long?
- Which specific side effects should I report to you after the surgery?
- What if the mesh surgery doesn't correct my problem?
- If I develop a complication, will you treat it or will I be referred to a specialist experienced with surgical mesh complications?
- If I have a complication related to the surgical mesh, how likely is it that the surgical mesh could be removed and what could be the consequences?
- If a surgical mesh is to be used, is there patient information that comes with the product, and can I have a copy?

After Surgery

- Continue with your annual and other routine check-ups and follow-up care. There is no need to take additional action if you are satisfied with your surgery and are not having complications or symptoms.
- Notify your health care provider if you have complications or symptoms, including persistent vaginal bleeding or discharge, pelvic or groin pain or pain with sex, that last after your follow-up appointment.
- Let your health care provider know you have surgical mesh, especially if you plan to have another surgery or other medical procedures.
- Talk to your health care provider about any questions you may have.

If you had POP surgery, but do not know whether your surgeon used mesh, ask your health care provider at your next scheduled visit.

FDA Activities:

The FDA is working in several areas to assess and improve the safety and effectiveness of urogynecologic mesh products. The FDA will:

- Convene the Obstetrics-Gynecology Devices Panel of the Medical Device Advisory Committee, on September 8-9, 2011.The panel will discuss and make recommendations regarding the safety and effectiveness of transvaginal surgical mesh for POP and SUI.
- Explore regulatory solutions to answer questions about the safety and effectiveness of urogynecologic mesh products that are now being marketed and those that will be reviewed for marketing in the future.
- Continue to monitor adverse events reported to FDA associated with surgical mesh used to repair POP and SUI, as well as assessing any and all data as it becomes available.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect a problem with surgical mesh, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program[2]. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements[3] should follow the reporting procedures established by their facilities. Device manufacturers must comply with the Medical Device Reporting (MDR) regulations[4].

To help us learn as much as possible about the adverse events associated with surgical mesh to repair POP and SUI, please include the following information in your reports, if available:

- Manufacturer's name
- Product name (brand name)
- Catalog number
- Lot number
- Size
- Date of implant
- Date of explant (if mesh was removed)
- Details of the adverse event and medical and/or surgical interventions (if required)
- Type of procedure (e.g., anterior or posterior repair, sacral colpopexy, sling procedure for SUI)
- Surgical approach: (e.g., vaginal, abdominal, laparoscopic)
- Reason for mesh implantation: (e.g., POP of the uterus, bladder, rectum, vaginal apex or bowel, SUI)
- Specific postoperative symptoms experienced by the patient with time of onset and follow-up treatment

Contact Information:
If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.

This document reflects the FDA's current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices.

Additional Information

- Urogynecologic Surgical Mesh Implants [5]
- Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse (July 2011) (PDF - 243KB) [6]
- Press Release: Surgical placement of mesh to repair pelvic organ prolapse poses risks [7]
- Federal Register Notice: Urogynecologic Surgical Mesh [8]
- Federal Register Notice Ammendment: Urogynecologic Surgical Mesh [9]

Links on this page:

1. /downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf
2. http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
3. /MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm
4. /MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm
5. /MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm
6. /downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf
7. /NewsEvents/Newsroom/PressAnnouncements/ucm262752.htm
8. http://www.gpo.gov/fdsys/pkg/FR-2011-07-14/pdf/2011-17695.pdf
9. http://www.gpo.gov/fdsys/pkg/FR-2011-08-15/pdf/2011-20644.pdf

EXHIBIT 6

Polymer Science & Material Chemistry

Exponent®

Expert Report of

Dr. Maureen Reitman

This document relates to:
C.R. Bard, Inc., Pelvic System Products Liability Litigation

United States District Court for the Southern District of West Virginia; Charleston Division
Bard Wave 9 Cases

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Expert Report of

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United States District Court for the Southern District of West Virginia; Charleston Division
Bard Wave 9 Cases

Prepared by:

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June 24, 2019

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Limitations

Exponent, Inc. ("Exponent") was retained by counsel for C.R. Bard to review documents, perform objective scientific analysis and provide opinions related to the Avaulta Pelvic Support System and Align Urethral Support System product liability litigation. This report summarizes work performed to-date and presents the findings resulting from that work. The findings presented herein are made to a reasonable degree of scientific and engineering certainty and/or probability. Exponent reserves the right to supplement this report and to expand or modify opinions based on review of additional material (e.g., additional medical records and defense expert reports) as it becomes available through ongoing discovery and/or through any additional work or review of additional work performed by others.

This report, and accompanying appendices, contains a summary of my opinions and the basis of my opinions, but should not be construed as complete or verbatim statement of my opinions or the basis thereto. I expect to answer questions related to my opinions and bases at deposition.

Executive Summary

The Avaulta Solo and Avaulta Plus pelvic mesh products and Align urethral sling (described herein collectively as "Bard TVM products") are implantable polypropylene meshes used for the repair of pelvic organ prolapse and stress urinary incontinence, respectively. The Align sling is provided as a strip of polypropylene mesh with characteristics similar to the arms of the Avaulta products. The shaped designs of the Avaulta meshes enable anterior or posterior repair, and the Avaulta Plus includes a porcine collagen-based layer in the organ-contact areas to provide the surgeon additional choices when addressing patient repair needs.

Implantable polypropylene mesh products have been used for the repair of soft tissue with clinical success since the 1960's; use in urogynecological applications has particularly increased since the 1990's. Review of design and manufacturing documents, regulatory submissions, and other material related to the Bard TVM products reveal medical devices developed and produced in accordance with accepted scientific, engineering and regulatory expectations for implantable medical devices. The development processes for both the Avaulta meshes and the Align sling synthesized prior experience, existing data, and product-specific information in a manner that reflected the state of the art in implantable medical product development, and generated information that formed the basis for FDA clearance and subsequent release to the market in June 2007. The three Bard TVM products have been engineered to have combinations of physical characteristics related to monofilament size, mesh structure, texture and porosity, as well as graft geometry and assembly, and are associated with effective repair and low recurrence rates.

Plaintiffs' experts allege that the Bard TVM products are defective in materials, design and manufacture. Specifically, Plaintiffs' experts allege that the polypropylene mesh degrades in the body, making it an unacceptable biomaterial. Plaintiffs' experts have previously asserted that the specific polypropylene used by Bard, Phillips Marlex HGX-030-01, is unacceptable because polypropylene may degrade by oxidation and because data sheet statements for the raw material indicate that the raw material supplier does not support its use in implantable medical devices. Plaintiffs' experts have previously associated adverse clinical outcomes with the

alleged oxidative degradation of the polypropylene in implanted Bard TVM products. However, no evidence of fracture or physical failure of implanted meshes has been provided, and these potential modes of failure are not identified in the complaint.

Polypropylene has been well characterized chemically and physically in the published literature and has a long history of safe use as a permanently implanted biomaterial. More specifically, Bard mesh products made from Phillips Marlex polypropylene homopolymer have been repeatedly evaluated for biocompatibility using standardized and accepted laboratory methods and animal models. Documents and literature confirm that polypropylene mesh products made in Bard-validated processes from Phillips Marlex polypropylene homopolymer resins have consistently demonstrated biocompatibility and functional performance for soft tissue repair in both abdominal and urogynecological procedures.

Plaintiffs' experts have previously reported that some portion of the subject explanted polypropylene meshes exhibit a brittle surface texture that includes predominantly circumferential cracking and assert that this texture is evidence of oxidation or, alternatively, environmental stress cracking (ESC) resulting from the interaction of cholesterol and the resin. However, direct examination and testing of explanted Bard's TVM and comparison to as-manufactured, intentionally oxidized and chemically challenged exemplar mesh, as well as review of related data from other sources, provides no evidence of oxidative degradation of the polypropylene in the body. While a brittle surface is visible on some portion of the subject explanted polypropylene meshes, it is not from polypropylene oxidation. Plaintiffs' experts' previous data can be reasonably explained by the presence of a surface deposit (e.g., a biofilm) that is more brittle than the polypropylene filaments, rather than the development of a brittle filament surface due to oxidation of the polypropylene. The presence of deposited biofilm is supported by data, such as chemical signatures distinct from those of polypropylene or oxidized polypropylene and non-combustible residues, as well as qualitative observations of film and crack morphology and depth. The presence of deposited biofilm also is consistent with expected biological processes in which proteins and cells adsorb to implanted surfaces, and the effect of post-explant fixatives such as formalin. Thus, Plaintiffs' experts have not provided a reasonable scientific basis for their previous assertion that the polypropylene is oxidized or

failing due to ESC, or that the alleged oxidation or ESC is associated with adverse clinical outcomes. It is my opinion to a reasonable degree of scientific and engineering certainty and/or probability that the cracked surface is actually a layer of a different material of biological origin, and not the alleged oxidized polypropylene.

Based on the information reviewed and my education, training and experience in the fields of materials science, polymer science and medical device product development, it is my opinion to a reasonable degree of scientific and engineering certainty that polypropylene, including Phillips Marlex HGX-030-01, is a reasonably selected biomaterial exhibiting appropriate biocompatibility. It is further my opinion to a reasonable degree of scientific and engineering certainty and/or probability that Bard TVM products based on Phillips Marlex HGX-030-01 polypropylene, exhibit the ability to perform as intended for tissue repair, including the repair of pelvic organ prolapse and stress urinary incontinence. It is also my opinion to a reasonable degree of scientific and engineering certainty and/or probability that the Avaulta Solo, Avaulta Plus and Align mesh characteristics, including geometric structure, pore characteristics, the incorporation of collagen and marking fibers, and biomaterial attributes, are reasonable for use in tissue repair, including pelvic organ and stress urinary incontinence repair, and are consistently described according to a reasonable method. There is no evidence of defective material, design, or manufacturing in Avaulta Solo, Avaulta Plus or Align implants, including those implanted in the Plaintiffs. Thus, it is my opinion to a reasonable degree of scientific and engineering certainty and/or probability that there is no evidence that the Avaulta or Align implants, or any action or inaction on the part of Bard related to these products, caused the alleged injuries for the Plaintiffs. All of my opinions expressed in this report are provided from the perspective of a biomaterials scientist and product development engineer, and are held to a reasonable degree of scientific and engineering certainty and/or probability.

The Executive Summary cannot encompass all of Exponent's technical evaluation, analysis, and conclusions. Hence, the main part of this report, supported by the various appendices, is at all times the controlling document.

1 Scope of Report

1.1 Scope of work

This report describes the materials, design, development, and performance of Avaulta Solo and Avaulta Plus meshes (Avaulta products), and the Align Urethral Support System (Align sling) sold by C.R. Bard for pelvic floor repair. Exponent has reviewed extensive documentation and testimony, and evaluated numerous explanted and exemplar meshes to investigate these topics in light of Plaintiffs' allegations that defects in Bard TVM material or design affect mesh performance. This report is provided for all associated Plaintiffs involved with this litigation. Throughout this report the term 'Plaintiffs' will be used to refer generally to any Plaintiff involved in this litigation.

1.2 Qualifications and Disclosures

I am a Principal Engineer, the Director of the Polymer Science and Materials Chemistry Practice, and a Corporate Vice President at Exponent. I hold two academic degrees: (1) a Bachelor of Science in Materials Science and Engineering from the Massachusetts Institute of Technology (MIT), and (2) a Doctor of Science in Materials Science and Engineering, with a thesis in the field of polymers, from MIT. I am a licensed Professional Engineer in the state of Maryland and am a Fellow of the Society of Plastics Engineers. I have been practicing in the field of polymer science and engineering for more than 25 years as a researcher at MIT, in a variety of technical roles at the 3M Company, and as a consultant with Exponent. I provide consulting engineering services in all aspects of polymer science and engineering including, but not limited to material selection, material characterization and documentation for regulatory compliance, product design and development, mechanical and chemical testing, microscopy and non-destructive imaging, failure analysis, polymer chemistry, polymer physics, and polymer processing.

I have experience in evaluation and testing of the physical properties and durability of polymers, in the determination of the formulation and chemistry that control these properties, and in the selection and specification of polymers for different applications. I have experience formulating

and evaluating polymer compositions, testing their properties and developing documentation, including material safety data sheets, associated with their use. I have been directly involved in product development, product line extensions, transfer of new products to manufacturing, qualification of alternative materials and manufacturing equipment, evaluating customer complaints, and performing root cause investigations. I have specific experience with the design, manufacturing and evaluation of medical devices made from polymeric materials; oxidation and oxidative stability of polyolefins including polypropylene; and the materials and manufacturing methods used for the Avaulta Solo, Avaulta Plus and Align products. I regularly work with clients to address questions related to medical device design, validation, and testing, and have presented my work in meetings with the Food and Drug Administration (FDA) as well as in training and lecture settings for members of the medical, medical device and plastics communities. I have lectured on the topics of material selection, plastics failure analysis, medical device failure analysis, advances in materials for medical devices, the materials science of polypropylene meshes, and aspects of medical device manufacturing. I am a past chairman and continue to serve as a member of the board of directors of the Medical Plastics Division of the Society of Plastics Engineers.

My *curriculum vita* is provided in Appendix A. A list of previous testimony is provided in Appendix B.

Exponent currently charges a rate of $710 per hour for my time. Other Exponent staff members with different bill rates have assisted me. No portion of our compensation is dependent on the outcome of this matter.

1.3 Information Considered

In the course of my analysis, Exponent has reviewed and relied upon documents, testimony, and examination of physical items, including portions of explanted materials, and a variety of exemplar meshes. A list of materials considered is provided in Appendix C, and a summary of Plaintiff-specific information is provided in Appendix D. I also relied on my education, general experience in the field, and knowledge acquired through years of research and consulting work

in the field of polymeric materials and medical devices. Specific documents and materials that I relied upon in reaching the opinions in this report are referenced throughout the text.

I have previously provided reports, data, analyses and testimony related to Bard's pelvic repair products litigation (MDL No 2187) and incorporate these by reference.

Although I have not prepared trial exhibits at this time, I may use any and all of the information described or referenced in this report. Additionally, I may use existing materials for demonstrative purposes.

2 Document Review and Analysis

This dispute is related to the materials, design, development, manufacture and performance of Avaulta Solo and Avaulta Plus meshes (Avaulta products), and the Align Urethral Support System (Align sling) sold by Bard for pelvic floor repair. Exponent has reviewed extensive documentation and testimony related to these topics in light of Plaintiffs allegations that defects in Bard TVM material, design or manufacture, and not factors related to individual surgical procedures and patient-specific characteristics and responses, are the cause of patient adverse outcomes. An overview of Exponent's analysis of the materials, design, development, manufacture and performance of the Bard TVM products is provided in this section, and supported by more detailed analyses in the attached appendices. The text and references are not intended to be exhaustive, but rather to disclose the bases for my opinions.

2.1 Bard TVM Mesh Materials

2.1.1 Overview of Surgical Mesh History

Surgical meshes are currently used in many different applications, including abdominal, urological, urogynecological, cardio-thoracic, and orthopedic applications (Pandit and Henry 2004). In traditional tissue defect repair, surgical techniques utilized the patient's own tissue to close the defect. These repairs, in the past, were performed using sutures under tension, but a mesh repair with little or no tension on the patient's tissue is preferred because of better overall outcomes (Cobb, Kercher et al. 2005). A synthetic mesh product is therefore employed as an integral part of the repair. The appropriate characteristics of a surgical mesh for tissue repair include numerous parameters such as chemical inertness and biocompatibility (Cobb, Kercher et al. 2005), resistance to infection, maintenance of long-term tensile strength, rapid incorporation into the tissue, adequate flexibility to prevent fragmentation, non-carcinogenic response, and the capability to restore natural movements of the anatomical area being treated (Pandit and Henry 2004).

Bard manufactures polypropylene meshes, which are appreciated for their excellent tensile and burst strength, resistance to infections, retention of physical properties, and ease of processing,

for soft tissue repair. The Bard product systems for stress urinary incontinence (SUI) and pelvic organ prolapse (POP) repair have a history that dates back to the early 1960s with the introduction of Marlex mesh, a simple monofilament polypropylene (PP) knit that could be cut to size by the physician (Usher 1963). Since its introduction as an implantable biomaterial in the form of sutures and mesh products in the 1960s, polypropylene has become one of the most widely used surgical polymers in the United States. (Usher, Allen et al. 1962, Usher 1963, Northey 1967, Pandit and Henry 2004, Hollinsky, Sandberg et al. 2008) Additional information on polymer surgical meshes and the design and materials of said meshes is provided in Appendices E, F, and G.

2.1.2 Mesh Characteristics

Meshes are generally described by their weight per unit area, pore size, and filament characteristics. Most of the test methods for evaluation of implantable meshes have been adopted from the American Society for Testing and Materials International (ASTM) specifications for the textiles industry (Cobb, Peindl et al. 2009), although there are aspects of mesh characterization (e.g., pore size) for which there are no standardized methods. The physical properties and handling characteristics of a mesh–based product depend on its "weight", as well as the material, the knit pattern (if applicable), and the construction of the mesh. An FDA guidance document for surgical meshes from 1999 describes additional properties to characterize the mechanical performance of meshes, including tensile strength of the mesh, device stiffness, suture pullout strength, burst strength, and tear resistance.[1] See Appendix F for additional information on mesh characteristics.

2.1.3 Vaginal/Pelvic Tissue Repair Products

The first synthetic polymeric mesh used for urogynecological applications was made from nylon (polyamide) and was reported to have been introduced in the 1960s (Choe 2003, Winters, Fitzgerald et al. 2006). The use of polypropylene in surgical meshes dates back to the 1960s,

[1] Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh, issued March 2, 1999

when Usher and the Phillips Corporation described the use of Marlex polypropylene woven mesh for hernia repair (Usher 1963). This was followed by additional reports of the efficacious use of polypropylene mesh, including Marlex polypropylene knitted mesh, for abdominal and urogynecological repairs (Morgan 1970, Morgan, Farrow et al. 1985). Subsequently, the use of prosthetic meshes, including those made of polypropylene, has become more popular for the treatment of POP (Julian 1996, Debodinance, Cosson et al. 2006) and SUI with the introduction of Tension Free Vaginal Tape (TVT) in the 1990s (Ethicon 1997). In 2014, 2016, and again in 2018, the American Urogynecology Society (AUGS) and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) issued a position statement about mesh midurethral slings including the Bard Align stating, "The monofilament polypropylene mesh mid urethral sling is the most extensively studied anti-incontinence procedure in history," and "Polypropylene mesh midurethral slings are a standard of care for the surgical treatment of SUI and represent a great advance in the treatment of this condition for our patients." The paper expands on this further, noting that polypropylene mesh is widely studied and recognized as safe and effective as a surgical implant(AUGS 2014, AUGS 2016, AUGS 2018).

In the treatment of both SUI and POP, surgical approaches including the use of mesh for tissue reinforcement have been aimed at improving the durability of the pelvic floor repair (Moore and Miklos 2009), while also enhancing the quality of life of the patient with the correction of any anatomical and functional derangements (Silva and Karram 2006). Similar to the mesh products used for hernia repair, meshes used in urogynecology have evolved to include additional layers such as collagen along with the polymer material, as well as the development and use of "vaginal mesh kits" for both POP and SUI indications. The wide variety of materials and products are tools for surgeons to provide options in light of the technique, personal preference, and patient-specific factors. Additional information on the evolution of surgical mesh products in urogynecology can be found in Appendix G.

Prospective, randomized, and controlled clinical studies comparing traditional approaches versus tension free vaginal tape use for the treatment of SUI provide perspective on the short-term and long-term outcomes of these procedures, complications, and the evolution of the surgical approaches toward the widespread adoption of these devices. These studies reflect

beneficial outcomes, complications that reflect the impact of a range a factors, and expected evolution in surgical approach and adoption. As would be expected for any surgically implanted device, the studies reported some complications (e.g., erosion, bladder injury, vaginal injury, urethral perforation, bladder obstruction, voiding difficulties, pain, hematoma, abscess, overactive bladder, infection, bowel injury, de novo urgency, and dyspareunia), as well as the effect of patient and surgical factors on the surgical outcomes. For example, there are studies on the positive outcomes (i.e. cure rates) following the implantation of Uretex (the predicate device to the Align), which also describe potential complications. The finding of a complication, such as erosion, is not indicative of a defective product. Specific complication rates in clinical literature need to be analyzed while considering the study type (retrospective, prospective, etc.), patient factors, and surgical factors before generalizations can be made from a single reported complication rate in the scientific literature. Additionally, prospective and retrospective studies provide an overview of clinical outcomes for the Align sling, as well as description of the potential complications, and how patient factors can impact the procedure's outcome. Similarly, prospective, randomized, and controlled clinical studies as well as retrospective studies comparing traditional approaches versus mesh use for POP have shown high success rates for mesh repair using Avaulta Solo, Avaulta Plus, and predicate devices. As with SUI, patient factors and surgical techniques have also been noted to be important factors in clinical outcomes for POP mesh repair. Additional information on SUI and POP repair outcomes, including outcomes of studies utilizing Avaulta Solo, Avaulta Plus and Align mesh products and other mesh and collagen products can be found in Appendix G.

2.2 Wound Healing and Biocompatibility

2.2.1 Healing Processes and Implanted Devices

When a medical device is placed in the body, the body elicits a cascade of responses, resulting from the injury to the tissues or organs involved, as well as the foreign body reaction to the implanted materials (Lin, Hirko et al. 1997, Portnoy 1998). Some level of foreign body response is anticipated and desired in soft tissue repair, and this is considered in the assessment of biocompatibility and device function. Protein adsorption is one expected and normal part of the foreign body response. Biofilms containing proteins and other biological materials develop

during normal healing processes, even in the absence of infections. The wound healing process for surrounding tissue includes a continuum of cellular events, including inflammation and the deposit of various biological materials. This process is known to be affected by patient-specific factors, including device placement, adequacy of tissue, and comorbidities. These factors can affect the nature of the interface between the device and repaired tissue structure, the rate and extent of tissue ingrowth, and the resulting geometric configuration of the device.

The extent and nature of scarring in a patient will affect the shape of the implant, as the implant will follow movement and contracture of the tissue. Any mesh implanted for tissue repair may exhibit shrinkage or contracture as a result of normal healing action on the implant, and identical products can exhibit widely varying levels of contracture because of implantation and patient-specific factors. Indeed, the literature reports an extremely wide range of results, even for identical meshes. Implantation factors include the initial placement shape, potential intraoperative folding during placement, the continuity of the surface that provides a foundation for tissue ingrowth, as well as the physician's approach for fixation. Patient factors include repair site location, previous medical history, geometry and access, as well as tissue quality. As a result, a reliable correlation between degree of shrinkage and mesh material or construction has not and cannot be made. For a more complete discussion on the wound healing process including contracture, please refer to Appendix H.

2.2.2 Biocompatibility

Biocompatibility has been defined as "the ability of a material to perform with an appropriate host response in a specific situation" (Boulanger, Boukerrou et al. 2008). Medical research has suggested an ideal biocompatible material to be inert, noncarcinogenic, strong, non-allergenic, non-inflammatory, capable of sterilization, convenient, and affordable. A well-accepted biocompatible material may still generate variations in response, including adverse reactions for some patients, because of the differences in the response to the same material between humans. Since its introduction for these purposes in the 1960s, polypropylene has been shown repeatedly to be a functional biomaterial according to these definitions (Usher 1963, Northey 1967, Frank 1968). Notably, polypropylene is recognized as an appropriate 'negative control' material for biocompatibility testing according to the International Standard ISO 10993.

Polypropylene is available in many grades, which typically differ in molecular weight (a property associated with flow and mechanical properties) and additives. When a particular grade is considered for use in food contact or medical devices, the grade is evaluated for leachables and extractables, and the response of the bulk and extracted materials are characterized in various laboratory tests. These *in vitro* tests are then followed by *in vivo* animal and clinical testing as necessary to provide an understanding of the physiological response to the material.

The FDA considers all available biocompatibility information, including history of clinical use, when reviewing medical device filings. Permanently implantable medical products incorporating Phillips Marlex polypropylene homopolymer have been repeatedly evaluated in these ways for decades.[2] Phillips[3] documents for Marlex HGX-030-01 confirm that the specific grade used in Bard's TVM products has been assessed for a variety of regulatory purposes and is manufactured in accordance with Good Manufacturing Practices (GMP) (CP-0088). Phillips reminds purchasers that "it is the responsibility of the customer to check compliance of the final articles with the relevant legislative and applicable regulatory requirements including restrictions" (CP-00090).

Additionally, the cleared use of Marlex HGX-030-01 polypropylene in a 2008 Boston Scientific 510k submission further supports the reasonableness of use of this material in a permanent implant for urogynecological repair. The submission included Phillip's Material Safety Data Sheet (MSDS), including the caution language related to permanent implants, and was reviewed by the FDA. The FDA made specific requests to Boston Scientific about the material, received historical and testing information, and ultimately cleared the device.[4] Phillips had entered into

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2 Usher, F. C. (1963). Hernia Repair with Knitted Polypropylene Mesh." Surg Gynecol Obstet 117: 239-240., DID-03-4663-1_Rev2_AVA2E0695015-AVA2E0695039 (Design input document for Align Sling), Trial Testimony of Roger Darois, p. 100 ll. 25 through pg. 101 ll. 10 (Trial Proceedings for MDL. No. 2:10-MD-2187, C.R. Bard, Inc., Pelvic Repair System Products Liability Litigation, as related to Donna and Dan Cisson)

3 Over time, Marlex has been manufactured by Phillips, Chevron Phillips, and Phillips Sumika. For purposes of this report, all of these entities will be called "Phillips"

4 See memo Michelle Berry to the FDA, dated July 18, 2008, subject: Premarket Notification – Abbreviated 510(k) – K081048 – Amendment 1

supply agreements with Boston Scientific to provide Marlex HGX-030-01 for their products. As part of the Pinnacle Pelvic Floor Repair Kit 510k process, Phillips also participated in discussions with Boston Scientific and was made aware of this end use. While Bard performed its own analysis and dealt directly with the FDA to obtain clearance for its specific products, this demonstrates the reasonableness of use of the Marlex HGX-030-01 for urogynecological repairs, and illustrates the secondary role of Phillips as a raw material supplier.

An MSDS[5] is not a biocompatibility document. It is an industrial communication related to occupational exposure to raw materials that is regulated by the Occupational Safety and Health Administration.[6] As part of the Department of Labor, OSHA's stated mission is "to assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance."[7] This stated mission is related to working conditions, and exposures that may occur while working, rather than in relation to the specific qualities of finished goods/articles[8], or exposures associated with the normal use of finished goods/articles including medical devices such as Bard TVM products.

Finished goods/articles do not require an MSDS for several reasons, including that the characteristics and performance of an end product (e.g., an implantable medical device) must be more comprehensively and differently assessed than by review of an MSDS regarding a raw material, and because the conditions of occupational use of the raw material (e.g., during bulk transport, storage, while extrusion processing, after sterilization, etc.) are not representative of the conditions of use of a converted or finished product. MSDS language does not affect the biocompatibility or function of the material.

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[5] Also known as a Safety Data Sheet (SDS)

[6] https://www.osha.gov/Publications/OSHA3514.pdf; https://www.osha.gov/enforcement/directives/cpl-02-02-038

[7] https://www.osha.gov/about.html

[8] Article is defined in 29 CFR 1910.1200(c) as "a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, *e.g.*, minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees." Articles are considered exempt from the Hazard Communication Standard (HCS): https://www.osha.gov/laws-regs/standardinterpretations/1999-11-01-1

MSDS language is intended to present potential industrial hazards that are not necessarily associated with end use. For example, the MSDS for table salt states that it is mutagenic for mammalian somatic cells and that one of the main precautions is "Do not ingest".[9] MSDS for phosphoric acid, a component of common sodas, contain statements such as "Very Hazardous in case of skin contact (irritant), of eye contact (irritant), or ingestion".[10] Warnings for bone cement, an accepted implantable polymer, state "May cause damage to organs through prolonged or repeated exposure".[11] These examples, among others[12], illustrate the importance of assessing specific exposure conditions and specific uses when considering risks and suitability for an application. In this case, Bard performed extensive testing, and had direct experience with performance in humans from years of use.

Similarly, raw material designations or labels such as "medical grade" are not a substitute for biocompatibility testing of a polymer, nor do the absence of these designations or labels preclude the material from being biocompatible, or preclude additional testing to confirm a specific product made from a raw material is biocompatible. Stated another way, the use of the term "medical grade" or MSDS language regarding implant use of raw materials does not inherently define the biocompatibility of the material, or the finished product using that raw material component. "Medical grade" is a market and/or business designation, not an industry-standard term with a specific meaning, and thus it means different things to different raw material suppliers and purchasers. For example, there are no industry-recognized standards that define the required characteristics of polypropylene marketed as "medical grade". Regardless of the designation or non-designation of a raw material as "medical grade", that material must undergo the stringent, aforementioned biocompatibility testing to support its use and clearance by the FDA as a component in a medical device. Furthermore, biocompatibility assessment of a medical device must consider more than just raw material characteristics including end use testing and evaluation of the device for regulatory approval or clearance.

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[9] Science Lab MSDS, updated 05/2013

[10] Science Lab MSDS, https://rsc.aux.eng.ufl.edu/_files/msds/332.pdf

[11] Stryker MSDS for Surgical Simplex® P Radiopaque Bone Cement, created October, 2014

[12] For example, water, play sand, sodium citrate, etc.

The FDA requires that the evaluation of any new device intended for human use include data from systematic biocompatibility testing to ensure that the benefits provided by the product will exceed any potential health and safety risks produced by device materials. The evaluation of biocompatibility includes a variety of tests, such as acute, subchronic and chronic toxicity, irritation to skin, eyes and mucosal surfaces, sensitization, hemocompatibility, genotoxicity, carcinogenicity, and effects on reproduction including developmental effects.[13]

According to the FDA's guidance on International Standard ISO 10993 (Biological evaluation of medical devices),[14] the biocompatibility or biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. ISO 10993 (Biological Evaluation of Medical Devices) is a global consensus standard developed based on decades of experience and relevant clinical history, and recognized by the FDA.[15] It provides an objective framework for testing and a recognized structure for communicating scientific information about biocompatibility. Other standardized methods for assessment of biocompatibility exist and are recognized as providing applicable information about biocompatibility. Product- and company-specific biocompatibility assessment programs use these objective tools to assemble relevant information for a particular product.

For a discussion on the evaluation of biocompatibility of materials, the FDA's guidance on the biocompatibility of medical devices and specifics to polypropylene biocompatibility, refer to Appendix I. Additional information related to biocompatibility of polypropylene and Bard

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[13] Blue Book Guidance G95-1, Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing', FDA, May 1, 1995; ISO 10993-1:2003 - Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing; ISO 10993-1:2009 - Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process

14 Blue Book Guidance G95-1, Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing', FDA, May 1, 1995

[15] ISO 10993-1:2003 - Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing; ISO 10993-1:2009 - Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process

mesh products based on Marlex HGX-030-01 polypropylene is provided in other Appendices, including J, K, L, and Z.

2.3 Avaulta Solo and Avaulta Plus Products

The Bard mesh-based products for tissue repair have a history that dates back to the 1960s, with the introduction of the Bard mesh, a simple monofilament polypropylene knit that could be cut to size by the physician. Building on Bard's experience and history with synthetic and animal-based tissue repair products, including Parietex Composite, Parietene, Pelvitex,[16] Collamend, and Avaulta Classic, Bard introduced the Avaulta Solo and Avaulta Plus products in the U.S. in June 2007.[17] While marketed, both products (hereby named as "Avaulta products") were available in two configurations for anterior and posterior repairs (Table 1).[18]

Table 1. Avaulta Solo and Avaulta Plus catalog numbers

Catalog No.	**Description**
486100	Avaulta Solo Support System, Anterior
486200	Avaulta Solo Support System, Posterior
486101	Avaulta Plus Biosynthetic Support System, Anterior
486201	Avaulta Plus Biosynthetic Support System, Posterior

2.3.1 Similarities with Predicate Products

The Avaulta Solo and Avaulta Plus products share many similarities in design with the predicate surgical mesh products, which includes the Avaulta Classic. These design similarities include the shapes, materials (polypropylene, porcine collagen), mesh fibers, and mesh knit structure. Specifically, the Avaulta Solo and Avaulta Plus products are shaped for the anterior and

[16] Also known as Sofradim's Ugytex

[17] AVA20010818-AVA20010819 (Authorization for release, AFR-03-4661-1 Rev 0)

[18] AVA20151469-AVA20151498 (International dossier, URO-07-005, dated Jun 28, 2007); AVA20023641-AVA20023683 (Customer preference evaluation and design - Validation summary report, CPE-03-4541-3 Rev 0); AVA20023525-AVA20023550 Avaulta Classic End Item product structure

posterior pelvic regions, building on the four-armed shapes of the anterior and posterior Avaulta Classic designs. The Avaulta products also utilize the same polypropylene resin as Bard's numerous surgical mesh products for hernia and pelvic tissue repairs. The addition of the acellular porcine collagen layer for the Avaulta Plus product also builds on the experience with porcine collagen on the Avaulta Classic and the collagen sheet of the Collamend product. Similar to the Avaulta Classic, the Avaulta Solo and Avaulta Plus products have dual knit structures. For a more complete review of the Avaulta Classic[19], refer to Appendix J.

2.3.2 Avaulta Solo and Avaulta Plus Product Development

2.3.2.1 Pre-Market Release

In November 2005, Bard initiated development of the concept and design for the Avaulta Solo and Avaulta Plus. This design comprises pre-shaped anterior and posterior implants for vaginal prolapse repair, utilizing previously demonstrated variable knit technology for the polypropylene components of the Avaulta Solo and Avaulta Plus. The Avaulta Plus also incorporated Bard's experience with combining collagen material and polypropylene in a composite implant. The development process benefited from the evaluation and known performance of existing designs, existing product specifications, manufacturing and test protocols, and insights developed from clinical experience with their own pelvic mesh floor reconstruction products, as well as those of their competitors. Validation of the design was based on feedback from the surgeons regarding the softness, flexibility, and smooth texture of the proposed Avaulta products compared to other mesh products, as well as observed functional anchoring of the mesh in cadaver tissue. The development process also included design qualification assessment, biocompatibility testing, and pre-clinical animal studies. For a more complete description of Bard's pre-market release development work, refer to Appendix K.

[19] Bard's Avaulta Classic products are pre-shaped meshes based on the Sofradim Ugytex dual knit mesh

2.3.2.2 Product Evaluation by Industry and Scientifically Accepted Standards

As part of the development process of the Avaulta Solo and Avaulta Plus products, risk management activities included a risk assessment conducted in accordance with ISO 14971 (Medical devices – application of risk management to medical devices) to assess potential risks associated with the use of the device and to ensure that benefits of the device outweigh the potential risks.[20] Risk assessment was also conducted in accordance with other international standards, such as the Medical Devices Directive (MDD 93/42/EEC) and ISO 13485 (Medical devices - Quality management systems - Requirements for regulatory purposes). [21]

The biocompatibility of the Avaulta Solo and Avaulta Plus implants built on the history of clinical use of Bard Soft Mesh, Avaulta Classic, Pelvitex (Ugytex), Collamend, and from testing of key biological parameters in accordance with industry wide and scientifically accepted standards. The evaluation of biocompatibility includes a variety of tests, such as acute, subchronic and chronic toxicity, irritation to skin, eyes and mucosal surfaces, sensitization, hemocompatibility, genotoxicity, carcinogenicity, and effects on reproduction including developmental effects.[22] The selection of tests is dependent on the intended uses of the device and the nature of contact (e.g., contact with tissue, bone, mucosal membrane, etc.), as well as the duration of contact (limited (<24 hours), prolonged (24 hours to 30 days), or permanent (>30 days)).[23] Accordingly, some of these tests are intended to evaluate short-term effects (e.g., acute toxicity, sensitization, and irritation to the skin, eye and mucosal surfaces), while others serve to

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[20] AVA20151469-AVA20151498 (International dossier; URO-07-005)

[21] AVA20152026-AVA20152071 (Checklist of essential requirements and standards (MDD 93/42/EEC) and checklist of essential principals, dated Jun 20, 2007, ERC030075 Rev 1); the MDD lists requirements regarding medical device design and involves a review of the essential requirements and standards, as well as essential principals. ISO 13485 is associated with the MDD in that it recommends procedures for a quality system that complies with the MDD.

[22] Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'; ISO 10993-1:2003 - Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing; ISO 10993-1:2009 - Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process

[23] Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'.

assess long-term or specific toxic effects (e.g., subchronic and chronic toxic effects, sensitization, genotoxicity, and carcinogenicity (tumorigenicity)).[24] As identified in ISO 10993, these tests may involve the use of extracts of the device's component materials or representative samples taken from the finished device, rather than the finished device itself.[25] For materials that have been well characterized physically and chemically, and have extended clinical history of safe use, demonstration of substantial equivalence is generally accepted by the industry and scientific community in lieu of all descriptive test methods contained within ISO 10993. Relying on biocompatibility evaluations of related devices, provided they include the same material, and are conducted in accordance with the guiding principles of ISO 10993 is typical and accepted industry practice. The assessment and interpretation of the outcome of these studies is conducted by expert assessors using suggested criteria as outlined in the respective standards for each test.

Thus, Bard acted as a reasonably prudent manufacturer by testing its products per ISO 10993, with these tests including cytotoxicity, sensitization, irritation and/or intracutaneous reactivity, acute systemic toxicity, genotoxicity, histological evaluation, hemolysis, pyrogenicity, subchronic toxicity, and chronic toxicity. Additional standardized testing on collagen products included viral inactivation, protein, lipid, and carbohydrate content (gravimetric method per ASTM D2257), chemical residuals analysis, tissue analysis (H&E Staining), crosslinking analysis, and the effect of in-process holding durations. Confirmatory biocompatibility testing on the final finished and sterilized product further included standardized USP[26] physico-chemical analysis, and gas chromatography-mass spectrometry,[27] as well as sensitization and

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[24] ISO 10993-1:2003 - Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing.

[25] ISO 10993-1:2003 - Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing (Section 5.1).

[26] United States Pharmacopeia

[27] AVA20153181-AVA20153183, AVA20153404-AVA20153405 (Summit anterior hybrid grafts (LR-6017) memo re: USP physico-chemical and cytotoxicity MEM elution testing, dated Oct 10, 2006, BIO-03-4661-5 and CHEM-03-4661-1); AVA20153208-AVA20153211, AVA20153213-AVA20153216, AVA20153407-AVA20153409 (Summit anterior hybrid grafts (LR-6040) memo re: USP physico-chemical and cytotoxicity (MEM elution and Toxikon protocol) testing, dated Apr 10, 2007, BIO-03-4661-11, BIO-03-4661-12, and CHEM-03-4661-5)

mucosal irritation studies,[28] which all demonstrated acceptable results and conformance with the test requirements. Animal studies were performed using rat, rabbit and sheep models, all providing results indicating the Avaulta Solo and Avaulta Plus products were acceptable and viable biomaterials.

Bard relied on existing clinical history and data from existing polypropylene mesh products to support the development and launch of the Avaulta Solo and Avaulta Plus products. While prototypes and specific experimental measurements were part of the development process, as would be expected, at no point were these products considered experimental. Indeed, given Bard's extensive history with polypropylene meshes and in pelvic soft tissue repair with existing products, these products were a reasonable extension of existing knowledge and demonstrated function, and had been appropriately validated prior to their commercial production. For a more complete description of the biocompatibility and animal studies, refer to Appendix L.

2.3.2.3 Post-Market Release Activities

Bard continued to be responsive to the market demands and clinical needs by iteratively evaluating the Avaulta Solo and Avaulta Plus products via complaint reviews. Bard learned of the potential for sterile abscesses that may occur upon exposure of porcine tissue to non-vascularized areas. Bard initialized a Corrective and Preventative Action (CAPA) investigation and determined that over-trimming of the graft in the distal-apical direction could potentially result in contact of the porcine collagen with the ischiorectal fossa. Bard implemented clarifications regarding implant trimming and adjustments. To assess any risks associated with this change, Bard reasonably and appropriately conducted a process failure mode and effects analysis (PFMEA)[29] as well as a design FMEA[30] (DFMEA).[31] Bard also evaluated potential

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[28] AVA20153185-AVA20153195, AVA20153197-AVA20153206 (Summit anterior hybrid grafts (LR-6013) memo re: sensitization (local lymph node assay) and vaginal mucosal irritation testing, dated Nov 1, 2006, BIO-03-4661-6 and BIO-03-4661-7)

[29] AVA20154258-AVA20154286 (RA-03000648 Rev 2, dated June 8, 2007 (PFMEA for Sling Integration))

[30] Failure Modes and Effects Analysis.

[31] AVA20154208-AVA20154257 (RA-03000615 Rev 2, dated June 11, 2007 (DFMEA for Sling Integration))

risks associated with the introduction of a new colorant, (phthalocyaninato (2-) copper), and slightly modified mesh fiber diameters. For a full review of postmarket release activities of the Avaulta Plus and Avaulta Solo, refer to Appendix O.

2.3.3 Avaulta Products Manufacturing Process

The manufacturing supply chain for the Avaulta Solo and Avaulta Plus products share many elements with broader Bard product lines; therefore, direct experience with both material and with manufacturing processes was available to draw upon. The Avaulta mesh is primarily constructed from Phillips Marlex HGX-030-01 monofilament polypropylene[32] supplied by Red Oak (Denver, NC) according to Bard's specifications.[33] The manufacturing process is a detailed, documented process that involves subprocesses such as filament and mesh manufacture, the addition of acellular porcine collagen for the Avaulta Plus, sterilization, and the assembly of the completed product. The process does not subject the polypropylene to unusual or uncontrolled temperature or shear profiles, and does not compromise the intended use or durability of the Bard TVM products. Prior to market release, Bard conducted manufacturing process validation testing and package qualification testing of the Avaulta Solo and Avaulta Plus products to verify that the manufacturing process meets the product specifications and requirements.[34] For a detailed description of the Avaulta Solo and Avaulta Plus manufacturing processes, please refer to Appendix Z.

2.3.4 Avaulta Products Regulatory Overview

On December 8, 2006, Bard filed a 510(k) premarket notification with the Food and Drug Administration (FDA) for the Avaulta Support System (Avaulta Solo Support System and

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[32] Phillips Marlex polypropylene mesh material has a long history of successful clinical use in hernia repair prostheses.

[33] AVA20016481-AVA20016487 (Davol certification/yarn traceability form for 0.0043″ fiber (RM3791147)); AVA2E0046846-AVA2E0046848 (Monofilament polypropylene, .0033″ diameter – raw material specification, RM0300703 Rev 1); AVA2E1040494-AVA2E1040495 (Polypropylene fiber, clear, 4.3 mil fiber – raw material specification, RM0300829 Rev 0/RM3791147)

[34] AVA20010785-AVA20010814 (Project requirements operating plan, Summit Anterior/Posterior Support System, dated Jun 25, 2007, PROP-03-4661-1 Rev 1)

Avaulta Plus Biosynthetic Support System) (K063712) and received clearance to market the devices on March 12, 2007. The materials and composition of the Avaulta Solo and Avaulta Plus products were stated to be similar to those used in Bard's Ugytex Dual Knit Mesh (K051503) and Bard/Davol Collamend Implant (K052322). A more complete description of the regulatory process followed and implemented by Bard, including references to all documentation, can be found in Appendix M.

2.3.5 Avaulta Products Risk Analysis

The Avaulta Solo and Avaulta Plus products were developed in accordance with internal procedures, which incorporate design input, output, review, verification, and validation. These procedures conform to the principles and intent of the FDA's design control guidance and Quality Systems Regulations (QSR; 21 CFR Part 820); the latter which incorporates Current Good Manufacturing Practice (cGMP). As previously mentioned, risk management activities included a risk assessment conducted in accordance with ISO 14971 (Medical devices – application of risk management to medical devices) to assess potential risks associated with the use of the device and to ensure that benefits of the device outweigh the potential risks. Risk assessment was also conducted in accordance with other international standards, such as the Medical Devices Directive (MDD 93/42/EEC) and ISO 13485 (Medical devices - Quality management systems - Requirements for regulatory purposes). This risk analysis for Avaulta Solo and Avaulta Plus products, which indicated that clinical trials before product marketing were not required, was appropriate and in accordance with the industry expectations for this type of medical device. For a more complete description of the Risk Analysis performed, refer to Appendix N.

2.3.6 Avaulta Products Postmarket Surveillance and Postmarket Risk Analysis

Post-product launch, Bard continued to monitor and perform diligent design review of the Avaulta Solo and Avaulta Plus products. From June 2007 through October 2008, Bard performed a review of complaints received of the Avaulta Solo implants and concluded that the Avaulta Solo continued to meet clinical expectations based on the reported complaint rate. Additionally, Bard performed a complaint review for the Avaulta Plus during the development

of a sewing pattern change to mitigate any potential new risks. Bard also conducted a risk assessment, which included a review of the design and process FMEAs, to identify potential new risks associated with the sewing change. A more complete description of the post market surveillance and risk analysis can be found in Appendix O.

2.3.7 Avaulta Product Instructions for Use

The instructions for use (IFUs) for each of the Avaulta Solo and Avaulta Plus reflect the intended use, contraindications, and potential risks of the products, as identified through the design process and risk assessment. The IFUs provide information to the surgeons regarding appropriate placement of the products, warn of potential adverse reactions and provide recommendations for post-operative actions to be avoided by patients. A more complete description of the instructions for use can be found in Appendix P.

2.4 Align Product

The Bard Align Urethral Support System is indicated for the treatment of female SUI resulting from urethral hypermobility and/or intrinsic sphincter deficiency.[35] While marketed, multiple kits were offered (Table 2), and each kit contained introducer needles specific to the surgical approach being used and a polypropylene mesh sling implant within an assembly sheath. The implantable mesh sling is constructed of knitted polypropylene mesh and the sheath assembly is a removable polytetrafluoroethylene tube with a Peel-Away tab. [36]

Table 2 Catalog Numbers for Align Products

Catalog No.	**Description**
BRD100R	Retropubic Kit
BRD200S	Suprapubic Kit
BRD300RS	Retropubic and Suprapubic Kit

[35] See AVA20155684 in AVA20155659-AVA20155931 (510(k) K070073 Align™ Urethral Support System)
[36] See AVA20155689 in AVA20155659-AVA20155931 (510(k) K070073 Align™ Urethral Support System)

BRD400HK	TO Hook Kit
BRD500HL	TO Halo Kit
BRD600HH	TO Hook and Halo Kit
BRD301RS	Retropubic suprapubic non-dilating
BRD601HH	Hook and Halo non dilating

2.4.1 Similarities of Align to Predicate Products

The Align Urethral Support System shares many similarities with its predicate surgical mesh product, the Uretex® TO Trans-Obturator Urethral Support System (510(k) K041176), including indications for use, intended use, fundamental technology, and design.[37] For a more complete comparison of the Align to predicate devices as well as a comparison of changes made upon submission of the Special 510(k) K093474 regarding design modifications, refer to Appendix Q.

2.4.2 Align Product Development

In February 2006,[38] Bard initiated development of the concept and design for the Align Urethral Support System. In the process of product development, Bard performed competitive product analysis to determine complaints and complications associated with competitor products and obtained surgeon feedback on multiple implant designs during defined design feasibility studies. Bard instituted product requirements based on specified material characteristics, conducted design verification and qualification on each component of the Align Urethral Support System and validated their final design with activities reflecting the types of validation studies outlined by the FDA. Upon release of the Align Urethral Support System, Bard received feedback about some connectors breaking due to technique as well as difficulty in removing the protective sheath from the mesh. Bard demonstrated its dedication to continuous improvement and

[37] See AVA20155687 in AVA20155659-AVA20155931 (510(k) K070073 Align™ Urethral Support System)
[38] See AVA20120232 in AVA20119742-AVA20120234 (Align DHF Volume 16)

addressed this feedback by modifying the design. For a more complete description of the Align Urethral Support System product development, refer to Appendix R.

2.4.3 Product Evaluation by Industry and Scientifically Accepted Standards

As part of the development process of the Align and Align TO products, risk management activities included a risk assessment conducted in accordance with ISO 14971 (Medical devices – application of risk management to medical devices) to assess potential risks associated with the use of the device and to ensure that benefits of the device outweigh the potential risks.[39] The risk assessment was also conducted in accordance with other international standards, such as the Medical Devices Directive (MDD 93/42/EEC) and ISO 13485 (Medical devices - Quality management systems - Requirements for regulatory purposes).[40]

Bard also performed a biocompatibility assessment per industry-wide and scientifically accepted standards. The Align mesh is made from the same resin as the Large Pore Soft Mesh and is manufactured using the same process, thus the biocompatibility assessment of the Align Urethral Support System was based on information related to Bard/Davol's Large Pore Soft Mesh, which incorporated testing of the Spermatex mesh. As previously discussed, reliance on predicate devices with equivalent materials of construction and a prior history of clinical utility is an industry-wide and scientifically accepted practice. The biocompatibility tests were performed in accordance with ISO 10993 and included intracutaneous reactivity, cytotoxicity, sensitization, chronic toxicity, hemolysis, muscle implantation, systemic toxicity, mutagenicity, and genotoxicity.

Additional testing was performed on the Align mesh and the introducer system according to ISO 10993-1. These tests showed the Align mesh and introducer systems are acceptable materials

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[39] See AVA20153846-AVA20153847 in AVA20153835-AVA20154203 (URO-07-004: Align Urethral Support System International Dossier, dated June 15, 2007)

[40] See AVA20154166-AVA20154189 in AVA20153835-AVA20154203 (URO-07-004: Align Urethral Support System International Dossier, dated June 15, 2007)

for contact with and implantation into the body. Further testing included USP physiochemical analysis (nonvolatile residues, residue on ignition, heavy metals, buffering capacity), GC/MS characterization, and infrared spectroscopy. Bard also performed animal studies to evaluate the tissue ingrowth and histological response resulting from implantation. For example, Bard performed an *in vivo* assessment of the Align in New Zealand White rabbits for 30 days and compared the results to the Uretex (the predicate to the Align) and the IVS Tunneller offered by Tyco Healthcare. Results showed similar neovascularization and minimal to no inflammatory cells surrounding the individual implants, demonstrating the biocompatibility of the Align.

Bard relied on existing clinical history and data from existing polypropylene mesh products to support the development and launch of the Align products. While prototypes and specific experimental measurements were part of the development process, as would be expected, at no point were these products considered experimental. Indeed, given Bard's extensive history with polypropylene meshes and in pelvic soft tissue repair with existing products, these products were a reasonable extension of existing knowledge and demonstrated function, and had been appropriately validated prior to their commercial production.. For further information regarding the biocompatibility testing and animal studies associated with the Align products, refer to Appendix S.

2.4.4 Align Manufacturing Process

The manufacturing process for the Align Urethral Support System shares many elements with broader Bard product lines and the Avaulta product lines. Just as with the Avaulta mesh products, the Align is constructed from Phillips Marlex HGX-030-01 monofilament polypropylene supplied by Red Oak according to Bard Specifications. The manufacturing process is a detailed, documented process that involves subprocesses including filament and mesh production, creation of the polytetrafluoroethylene sheath, kit assembly and sterilization. For a more complete description of the Align manufacturing processes, please refer to Appendix Z.

2.4.5 Align Regulatory Overview

On January 5, 2007, Bard submitted a 510(k) premarket notification to the Food and Drug Administration (FDA) for the Align Urethral Support System (K070073)[41] and received clearance to market the devices on March 21, 2007.[42] The Align shares the same indications for use, intended use, fundamental technology, and design with the Uretex TO Trans-Obturator Urethral Support System manufactured by Sofradim Production (K041176).[43] Within the regulator overview, Bard performed physicochemical and biocompatibility testing in accordance with ISO 10993 (Biological Evaluation of Medical Devices),[44] as well as functional device testing in accordance with FDA Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh (March 2, 1999).[45] On December 2, 2009, Bard submitted a Special 510(k) premarket notification (K093747) to notify the FDA of design changes to the predicate Align Urethral Support System (K070073),[46] and received clearance to market the device with the modifications on May 7, 2010.[47] For a more complete description of the regulatory process undertaken by Bard in the development and release of the Align Urethral Support System, refer to Appendix T.

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[41] See AVA20155669 in AVA20155659-AVA20155931 (510(k) K070073 Align™ Urethral Support System)

[42] See AVA20155841 in AVA20155659-AVA20155931 (510(k) K070073 Align™ Urethral Support System)

[43] See AVA20155687 in AVA20155659-AVA20155931 (510(k) K070073 Align™ Urethral Support System)

[44] See AVA20155694-AVA20155695 in AVA20155659-AVA20155931 (510(k) K070073 Align™ Urethral Support System); the polypropylene used for the Align is the same material used in Bard's Large Pore Soft Mesh with the same ISO 10993 contact profile so only chemical assay confirmation tests were done to confirm bioequivalence of the material.

[45] See AVA20155696-AVA20155708 in AVA20155659-AVA20155931 (510(k) K070073 Align™ Urethral Support System)

[46] See AVA20162165 in AVA20162160-AVA20162416 (Special Premarket 510(k) Notification K093747: Align® Urethral Support System Dilator)

[47] See AVA20162407 in AVA20162160-AVA20162416 (Special Premarket 510(k) Notification K093747: Align® Urethral Support System Dilator)

2.4.6 Align Risk Analysis

The Align and Align TO products were developed in accordance with internal procedures, which incorporate design input, output, review, verification, and validation.[48] These procedures conform to the principles and intent of the FDA's design control guidance[49] and Quality Systems Regulations (QSR; 21 CFR Part 820); the latter which incorporates Current Good Manufacturing Practice (cGMP). As part of the risk assessment, Bard considered the complaints associated with the Uretex product, and conducted a process failure mode and effects analysis (PFMEA)[50] as well as a design FMEA (DFMEA)[51] during the development of the Align and Align TO products. Bard implemented design improvements based on the results of these analyses. This risk analysis for the Align products, which indicated that clinical trials before product marketing were not required, was appropriate and in accordance with the industry expectations for this type of medical device. For a more complete review of the Align risk analysis, refer to Appendix U.

2.4.7 Align Post-Market Surveillance and Risk Analysis

Following market release in June 2007, Bard continued to review field response to the product, including complaint information for the Align sling.[52] Complaints were principally (approximately 80%) associated with the connectors, with the majority of other complaints associated with handle and sheath removal. Bard also reviewed complaints associated with predicate and competitor products, as demonstrated by the updated complaint summaries in April 2008,[53] 10 months after product launch. Through this review process and subsequent implementation of design changes, Bard was able to cut in half the number of complaints per 10,000 units regarding the connector design. The review did not indicate a need for

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[48] AVA20113826-AVA20113850 (PROP-03-4663-1 Rev 2, dated June 15, 2007)

[49] Design control guidance for medical device manufacturers, issued March 11, 1997

[50] AVA20154258-AVA20154286 (RA-03000648 Rev 2, dated June 8, 2007 (PFMEA for Sling Integration))

[51] AVA20154208-AVA20154257 (RA-03000615 Rev 2, dated June 11, 2007 (DFMEA for Sling Integration))

[52] See AVA20120741 in AVA20120732-AVA20120754 (DID-03-4663-1 Rev 0, dated Oct 27, 2006)

[53] See AVA2E0080598, AVA2E0080609-AVA2E0080610 in AVA2E0080598-AVA2E0080620 (DID-03-4900-1 Rev 1, dated April 21, 2008)

modification of the implanted mesh. For a more complete review of the post-market surveillance, refer to Appendix V.

2.4.8 Align Instructions for Use

The instructions for use (IFU) of the Align and Align TO Urethral Support Systems reflect the intended use, contraindications, and potential risks of the product, as identified through the design process and risk assessment. They include warning language and surgical techniques specific to the insertion kit. Additionally, Bard continued to provide periodic updates to the IFU's to address the design modifications made post-market release. For a more complete description of the IFU's, refer to Appendix W.

2.5 Align and Avaulta Product Development Activities

The Bard TVM products were developed in parallel, with significant overlap in aspects of product development including concept, feasibility studies, development, and product launch.[54] The products shared Bard's long history of clinical success with polypropylene mesh products for soft tissue repair, including those based on Phillips Marlex HGX-030-01. Many features of the Bard TVM products were shared, including the same resin, the same mesh production process, shared direct and associated project personnel, and company knowledge of materials, manufacturing, and testing. Additionally, the Align knit construction is the same as that used in the arms of the Avaulta Solo and Avaulta Plus. All of the Bard TVM products (Avaulta Solo, Avaulta Plus and Align) received FDA clearance and were released to market in June 2007. Additional information on the Align and Avaulta crossover, including a graphical representation of the timeline, can be found in Appendix X.

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[54] Documents that recorded the initiation of the various phases of the medical device development process were included in the Align DHF volume 16 and Avaulta DHF volume 6; for example, see AVA20011083-AVA20011089 in AVA20010672-AVA20011100 (Avaulta DHF volume 6: PIF-03-4661-1 Rev 0); AVA20120232-AVA20120234 in AVA20119742-AVA20120234 (Align DHF volume 16: PIF-03-4663-1 Rev 0); AVA20011090-20011093 in AVA20010672-AVA20011100 (Avaulta DHF volume 6: PIF-03-4661-2 Rev 0); AVA20120229-AVA20120231 in AVA20119742-AVA20120234 (Align DHF volume 16: PIF-03-4663-2 Rev 1)

3 Mesh Testing and Analysis

Exponent has systematically evaluated the characteristics and condition of explanted and exemplar materials associated with the Avaulta and Align products in light of the allegations of oxidative degradation and lack of stability asserted by the Plaintiffs. Materials evaluated included polypropylene pellets,[55] mesh stock,[56] exemplar Avaulta Solo, Avaulta Plus and Align meshes,[57] as well as explanted mesh from this litigation and prior litigation.[58] Materials were evaluated in the as-received condition, and after being subjected to various treatments designed to remove tissue[59] as well as after treatments designed to provide chemical, thermal and radiation challenges to the material stability. Companion analyses, such as analysis of the cleaning solutions and intentionally dissolved portions of the mesh, were also performed. The materials were destructively and non-destructively evaluated according to test protocols developed from standardized methods, and compared to pristine and intentionally oxidized controls prepared from exemplar mesh. In some cases, comparative analyses were limited by the amount of available material and/or the condition in which the material was provided. To date, Exponent has directly evaluated explants from at least 99 individuals, and repeatedly tested portions of at least 10 lots of exemplar TVM products for control and reference purposes. Through the course of this test program, Exponent has found no evidence of *in vivo* oxidation of Marlex polypropylene or the Bard products made from them.

Exponent evaluated materials visually, microscopically, chemically, and thermally using techniques including optical microscopy (OM), Scanning Electron Microscopy (SEM), energy dispersive spectroscopy (EDS), Focused Ion Beam (FIB) milling, Fourier transform infrared spectroscopy (FTIR), gas chromatography-flame ionization detection (GC-FID), liquid

[55] HGX-030-01 resin

[56] Greige Goods, lot #SA0300122, Exp: 2039-12-30

[57] Numerous exemplars have been evaluated in various ways. Lots include HUXG1273, HUXG1273, BMUD0023,BMUF0017, BMWB0002, BMWB0001, HUUC0511, HUWD1725, HUUC0510, HUWD1725, HUWE0592

[58] Evidence and reference or control items were received and tracked according to chain of custody procedures.

[59] Cleaning procedures are described in various Appendices.

chromatography (LC), differential scanning calorimetry (DSC), gas chromatography-mass spectroscopy (GC-MS), thermogravimetric analysis (TGA), oxidation induction time testing (OIT), as well as by chemical immersion, QUV exposure, dissolution testing, and immersion in biological serum. Data was collected at Exponent or at Exponent's direction, and all analysis was performed or verified by Exponent.

3.1 Cleaning

While this section of the report discusses the general cleaning procedures and analysis of explants performed by Exponent, more detailed plaintiff specific information in relation to this litigation is provided in Appendix D.[60] In all cases, mesh arrived embedded with tissue and other biological matter. Explant samples were generally received in formalin, a disinfectant and fixative that chemically alters the tissues associated with the explant, although some explants were previously received in a dry condition. Formalin will crosslink the tissue, creating tissues that are more difficult to remove; the difficulty increases with formalin exposure time (Putchler 1985; Fox 1985, Shelby 2017).

Exponent has previously evaluated a range of cleaning solutions and conditions in an iterative manner to attempt to fully remove the biological materials attached to the explant surfaces.[61] The cleaning chemicals and protocols were developed from available protocols, standards and literature information,[62] and performed according to standard protocols similar to that described by Thames, et al.[63] and as detailed in reports submitted previously for MDL Waves 4-8.

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[60] Exponent received and analyzed an explant from two plaintiffs in this litigation (Plaintiffs: Becky Smith and Gladys Katsiafas). The results of this analysis are provided in Appendix D. Additionally, Exponent understands that an explant exists for Plaintiff Donna Chrastecky. Exponent reserves the right to analyze the explant from Donna Chrastecky and supplement this report at a later date with the results of that analysis.

[61] Mesh was evaluated after immersion in sodium hypochlorite (bleach), hydrogen peroxide, nitric acid, sodium hydroxide, xylene, hexane, isopropyl alcohol, dimethyl sulfoxide, Proteinase K, Tergazyme, deionized water, iodine, betadine and hydrochloric acid as well as Aqua Regia and potassium iodide solutions.

[62] 2011; Choma et al., J Spinal Disord Tech, 2009; Baxter et al., J Biomed Materials Res Part B: Applied Biomaterials, 2009; Guidoin et al., Biomaterials, 2000; de Tayrac and Letouzey 2011

[63] Thames, SF, White, JB, Ong, KL *The myth: in vivo degradation of polypropylene-based meshes*, Int Urogynecol J, 2016, 1-13.

Briefly, the explants were repeatedly immersed in sodium hypochlorite (NaOCl) solution (bleach, which is a solution of 10-15% NaOCl in water) followed by immersion in deionized water to remove the bulk tissue. The explanted mesh material was then soaked in a 0.8 mg/mL solution of Proteinase K in tris-buffered saline (TBS) to further break down biological material present as a crust or other debris on the surface of the mesh fibers, followed by a final cleaning in an NaOCl solution. Explanted mesh and associated materials were visually examined, photodocumented, and analyzed via gravimetry, attenuated total reflectance Fourier transform infrared spectroscopy (ATR-FTIR), optical microscopy, scanning electron microscopy[64] (SEM), and Energy-Dispersive X-ray spectroscopy (EDS) throughout the cleaning process. Exemplar materials were also subjected to this protocol and as expected, the polypropylene was highly resistant to damage by the cleaning protocols.

Methods of tissue removal vary between experts and have differing levels of success. Although portions of the mesh fibers may be visible in as-received explants, attached tissue must be removed to properly observe the implanted mesh fibers. Immersion of samples in bleach, as has been shown in previous Exponent reports and literature (Thames, White et al. 2017), is a generally effective method to remove bulk tissue. Some explants, especially explants with shorter implantation times (e.g., less than about one year), are readily cleaned to reveal the intact fiber originally obscured by biological materials. Experience has shown that longer water soaking does increase the amount of crust removal, which is consistent with that reported by Thames and colleagues. Figure 1 is an example of a portion of mesh prior to cleaning; biologic tissue is visibly present. Shown in Figure 2 is this same mesh after 15 minutes of cleaning via immersion in bleach on an orbital shaker. The surface crust is partially intact and curling away from the underlying fiber, providing some insight into the mechanical properties of this crust. Notably, the fiber underneath has the appearance of pristine mesh.

[64] Within the limitation created by tissue presence and mechanical handling, SEM images were taken at multiple identical locations throughout the cleaning process.

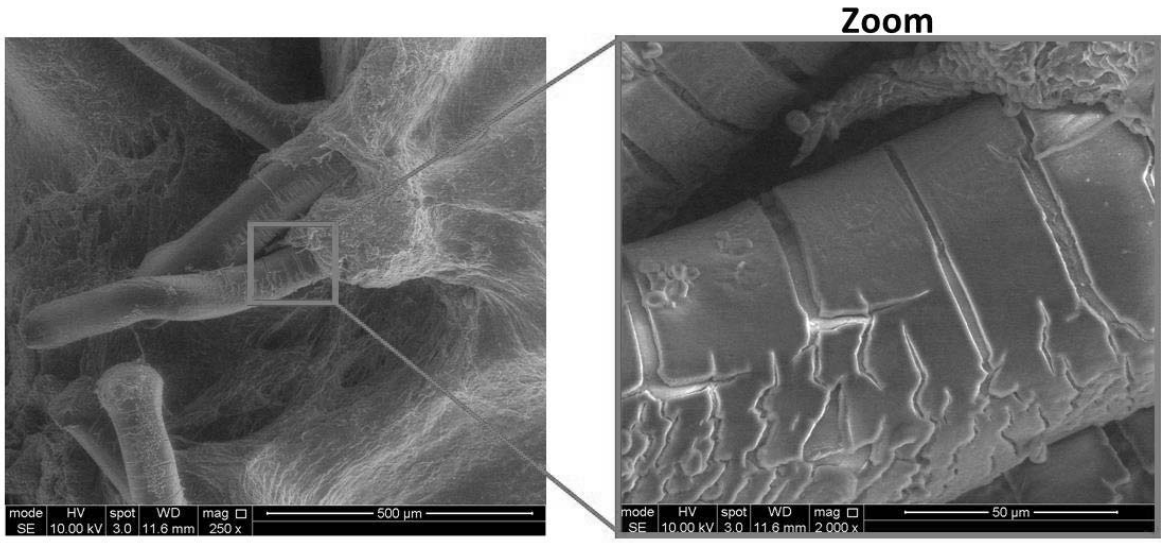

Figure 1. SEM of Smith explant prior to cleaning reagent exposure.

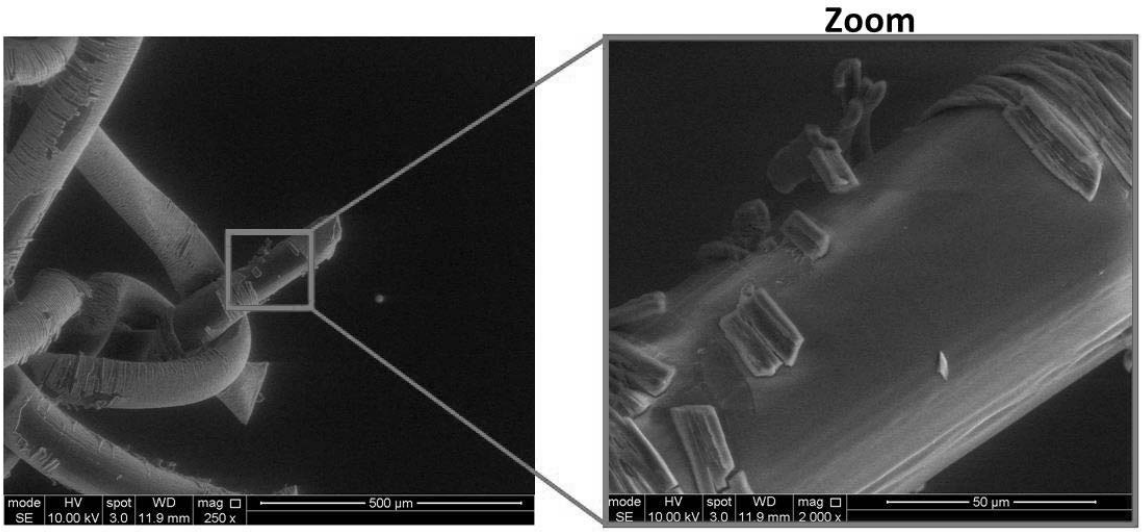

Figure 2. SEM from the same explant as Figure 1, after partial cleaning (25 minutes) in bleach. The crust is peeling and curling away from the fiber as a broken layer, revealing a smooth fiber surface consistent with pristine mesh.

Removal of the biological materials requires a combination of time, solvent action, and mechanical assistance. To provide a more complete cleaning the bulk tissue removal step should be combined with sonication, as this appears to assist in the removal of the distinct surface layer covering portions of the mesh. The importance of cleaning was highlighted by de Tayrac (de Tayrac and Letouzey 2011), who was able to mimic the cracked surface appearance of polypropylene mesh filaments reported by other authors by inducing the development of a

brittle film on mesh fibers and then remove the film to reveal the intact filaments after proper cleaning (Figure 3).[65]

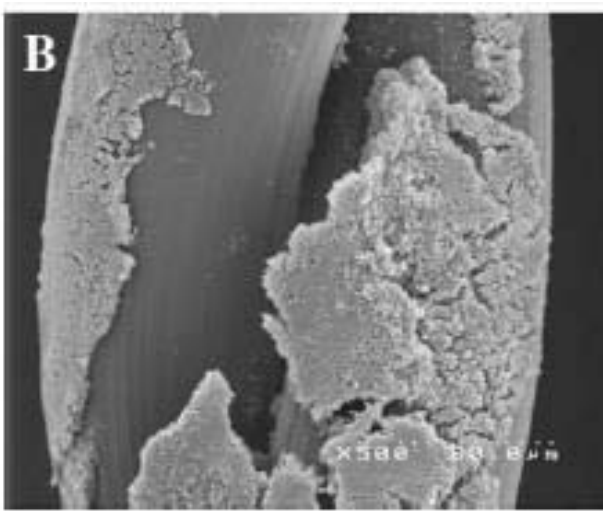

Figure 3. Figure from De Tayrac (2011) showing crust around a pristine PP fiber

Exponent's cleaning protocols incorporate exposure to bleach (10-15% sodium hypochlorite solution) under orbital shaking and sonication, incubation in distilled water at 80 ˚C, and a second step that includes exposure to proteinase K under incubation at 58 ˚C. Interim observations and testing of explants and associated solutions demonstrates that gross soft tissue removal is relatively straightforward, and the majority of softer materials can be removed with a few hours of cleaning in a sodium hypochlorite solution (i.e., bleach). When cleaning was performed by plaintiffs' experts in the previous litigation[66], they generally followed this procedure. However, evidence of biological material on the surface of the mesh fibers (i.e. a crust and in some cases additional softer tissue) remains on previous plaintiffs' samples.

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[65] In light of the observation that a brittle film on the polypropylene surface may appear similar in some ways to the brittle surface that can result from oxidation of polypropylene, it is important to carefully consider the capabilities and limitations of test methods used to characterize explants. Exponent's analysis incorporates multiple complementary techniques in order to assess the explant surface for evidence that oxidation caused the observed cracking, or if the cracking was present in a deposited material that had not been removed by the applied cleaning methods.

[66] Plaintiffs' experts did not perform explant cleaning/analysis for the aforementioned plaintiffs, thus, reference is made to previous analysis performed by Plaintiffs' experts.

Additional cleaning actions through extended immersion in bleach and Proteinase K as well as repeated sonication as in Exponent's cleaning protocols continue to remove the biological deposits, though the amount of material to be removed and rate of removal vary by plaintiff and are not directly associated with implantation time. When cleaned, the original, uncracked morphology of the fibers is visible including extrusion lines and pristine, smooth surfaces. No evidence of dissolution or degradation of the polypropylene resin is found by analysis of the fibers or the cleaning solutions. In most cases, however, a portion of the deposit is more resistant to removal and remains as a cracked crust on the surface. Figure 4 below is a comparison of identical locations on an explant that has been successively cleaned. The left image is after the first NaOCl cleaning, the right is after the final NaOCl cleaning step. Clearly the majority of the crust has been removed with extrusion lines and pristine fiber visible after the final cleaning step.

The removal of additional biological materials after cleaning steps beyond a short bleach immersion can be observed physically and chemically. For example, the coating coverage and apparent thickness is reduced (Figure 4), and this is reflected in chemical measurements after the first bleach step of functional groups by FTIR and elements by EDS. For example, the relative intensity of amide-type FTIR absorbance bands decreases after increased bleach immersion (Figure 5) while EDS (Figure 6) shows that the crust portion of an explant contains multiple atomic species (e.g., sodium, sulfur, and chlorine), that are not associated with pristine mesh and are not present on the exposed, smooth fiber underneath despite similar bleach exposure.

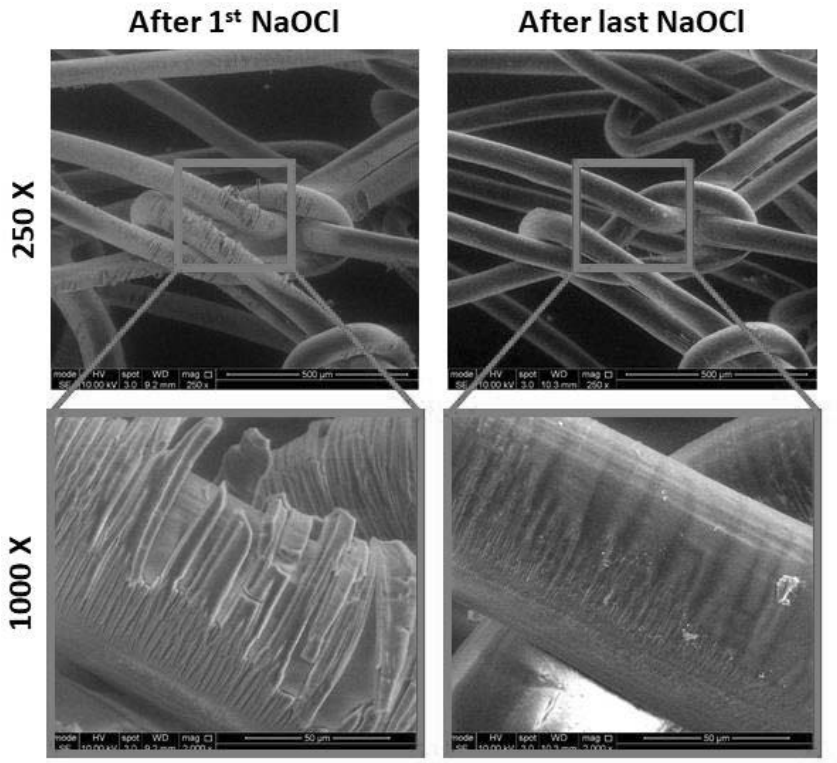

Figure 4 Comparison of first cleaning and last cleaning of the Katsiafas explant. The majority of the crust has been removed, revealing the uncracked fiber, including typical extrusion line features of a pristine fiber, underneath the crust. (Images from the same location at different points in the cleaning process).

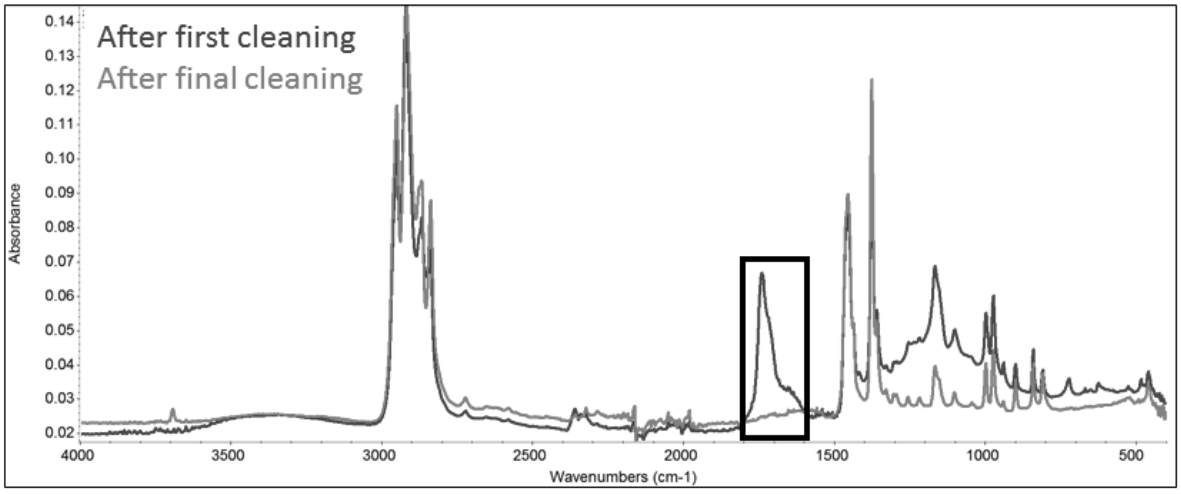

Figure 5 FTIR Comparison of an explant showing FTIR spectra after the first cleaning step (blue) and after the final cleaning step (red). The peaks in the 1600-1800 cm^{-1} range and 3000-3700 cm^{-1} range are significantly reduced or no longer present, indicating removal of the source of the related functional groups.

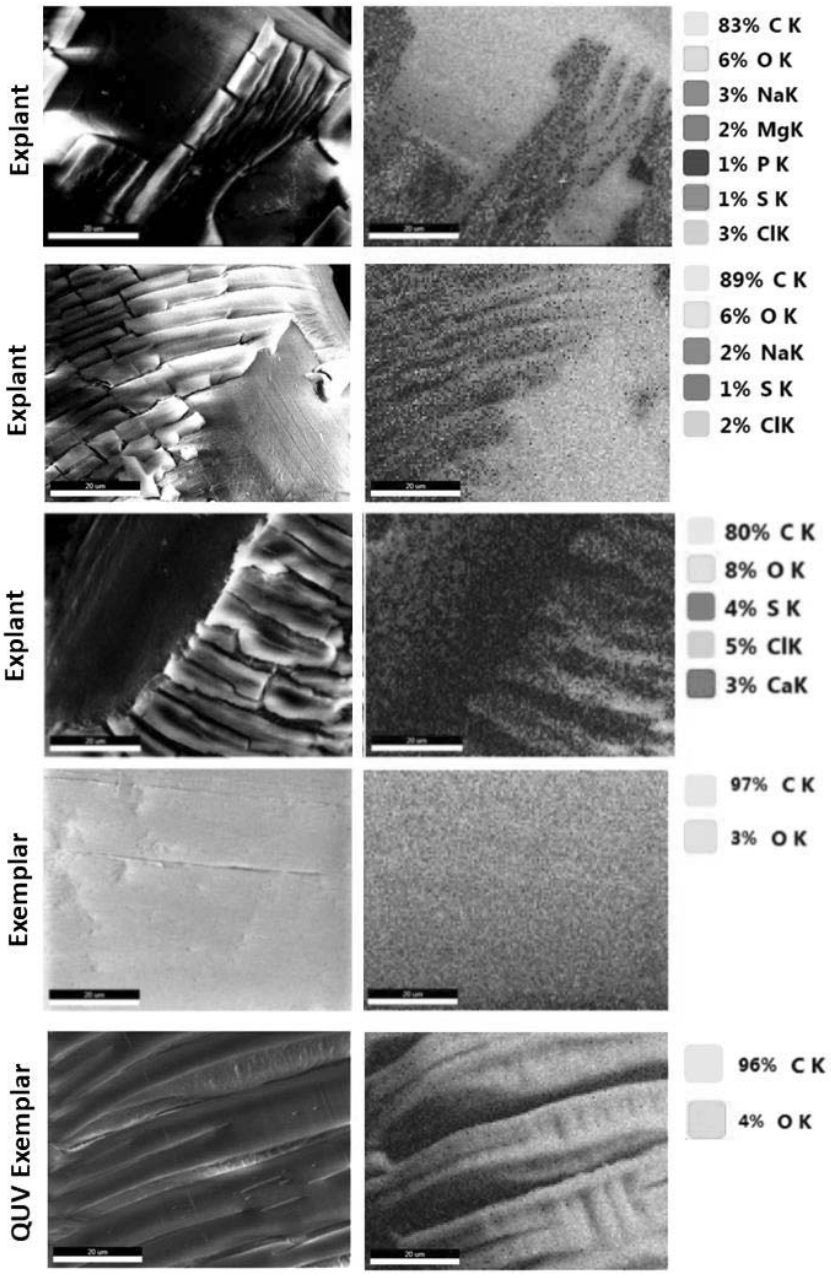

Figure 6 EDS map[67] of three different explants after the first bleach cleaning step illustrating compositional differences between the cracked crust and the underlying smooth fiber. EDS maps of an exemplar and an intentionally oxidized exemplar (QUV) after the first bleach cleaning step do not contain atomic species like sodium, chlorine, sulfur, etc. that may be associated with explants.

[67] Percentages of elements detected are semi-quantitative due to sample geometry, analysis area, and possible compositional differences throughout the sample.

Visual, FTIR, and GC-MS analysis of cleaning solutions do not indicate the presence of oxidized polypropylene in the sample. Instead, particulate can be observed in the initial cleaning step solutions, indicative of the bulk tissue removed from the explanted mesh, while later solutions are free of particles or detectible films of polypropylene-based material.

3.2 Visual and Microscopic Condition

3.2.1 Exemplar Materials

When examined visually and microscopically, the pristine pellets, greige goods (GG), and mesh products exhibit the typical and expected appearance of polypropylene in these various stages of manufacture. Optically, filaments in the mesh are clear. When examined at higher magnification, the normal surface effects of extrusion and the expected effects of heat setting, such as extrusion lines, are visible on the greige goods and mesh products. These features have no functional effect on the strength or durability of the filaments as used in the Bard TVM products. The range of normal features is not specific to a lot and is representative of the condition demonstrated by any Marlex polypropylene mesh produced by or for Bard. Photographs, optical micrographs, and SEM micrographs are provided throughout the Appendices.

The mesh products do not exhibit any evidence of improper manufacturing, excessive heat history, or non-conformance with the qualified manufacturing process. Thus, to the extent that variations in surface striations, surface nicks, peels or distortions, or changes in fiber roundness are present, they would have been functionally assessed during Bard's various product development activities, including biocompatibility, physical property evaluation and functional testing. They are considered normal and not detrimental to the capability and function of the product. There is no evidence of material changes that would alter the biocompatibility or performance of the material from that assessed during qualification and use of this polypropylene and the Bard TVM products.

The material also dissolves in boiling xylenes as expected, and when dried from solution, exemplar material creates an opaque film with a visible crystalline structure. Similar treatment

of cleaned explants results in an opaque film with larger crystallites and an overall different appearance. EDS analysis in the SEM reveals the presence of foreign nucleating material in the explant samples. A more detailed description of the xylene dissolution results is provided in Appendix HH.

3.2.2 Explant Mesh

When examined visually and microscopically after various gross tissue removal procedures, explanted mesh products exhibit the same basic configuration as pre-implant mesh and are physically intact except where cut or otherwise altered during placement or removal of the mesh. No signs of physical overload failures are present. As noted above, variability in the extent of material removal accomplished by the standardized cleaning methods is observed.

Optically, the filaments in the mesh are cloudy or opaque in most areas after cleaning. When examined at higher magnification, a surface texture that is not present on the exemplar, never-implanted mesh is observed. This texture is consistent with the presence of an outer layer that is more brittle than the underlying polypropylene filament. The layer can be inferred to be brittle based on the cracking, with reduced resistance to elongation compared to the underlying fiber, though the deformation reflected by curled or rolled portions indicates a level of physical integrity not typically associated with an oxidized polypropylene layer. Importantly, the morphology alone is not sufficient to determine the chemical composition of the outer layer, and therefore cannot be used as a stand-alone basis for determining that the observed surface texture is the result of fiber degradation or consists of oxidized polypropylene.

EDS spectra collected during SEM imaging are likewise not capable of providing molecular composition. EDS provides elemental (not molecular) information, and does not measure the presence of all types of atoms. Thus, the presence of oxygen is not sufficient to determine if the material is oxidized polypropylene or some other material with brittle properties. For example, oxygen is also present in amide-containing materials such as those present in biological materials. As a result, a simple ratio of carbon and oxygen peaks is not a reliable measure of oxidation of the polypropylene mesh.

SEM provides a number of insights about the crust based on morphology of the surfaces, cracks, and underlying material morphology. Bare sections of undamaged polypropylene are seen under the crust. Bare sections can result from cleaning or mechanical dislodgement (Figure 7) of the surface deposit, though in some areas, shielding due to mesh geometry may have reduced or prevented the formation of the layer. These bare spots do not have the appearance or distribution that would be expected if the observed cracking were associated with oxidative degradation. The revealed fiber surface does not exhibit checking or crack tip penetration as would be expected if it were oxidized, while the cracked layer is observed to curl back on itself (Figure 8), a behavior not observed in intentionally oxidized polypropylene fibers. Notably, the brittle crust layer on explants is generally well defined (Figure 7-Figure 9), and the fibers of the cleaned explants show evidence of ductility that would not be found in embrittled, oxidized polypropylene (Figure 10). Furthermore, the brittle layer on explanted filaments does not exhibit the expected variable crack depth that would be associated with progressively oxidized material (Figure 12 and discussed further below).

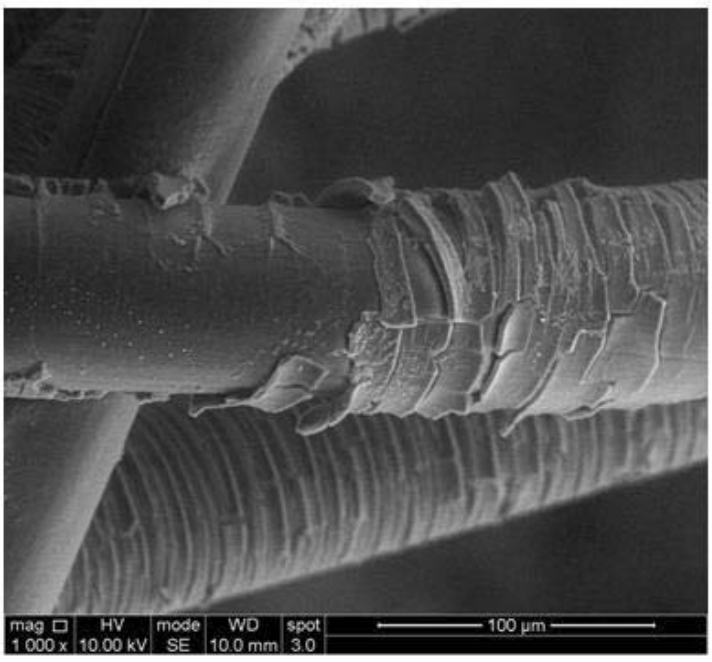

Figure 7 SEM image of an explant showing areas of exposed, uncracked polypropylene.

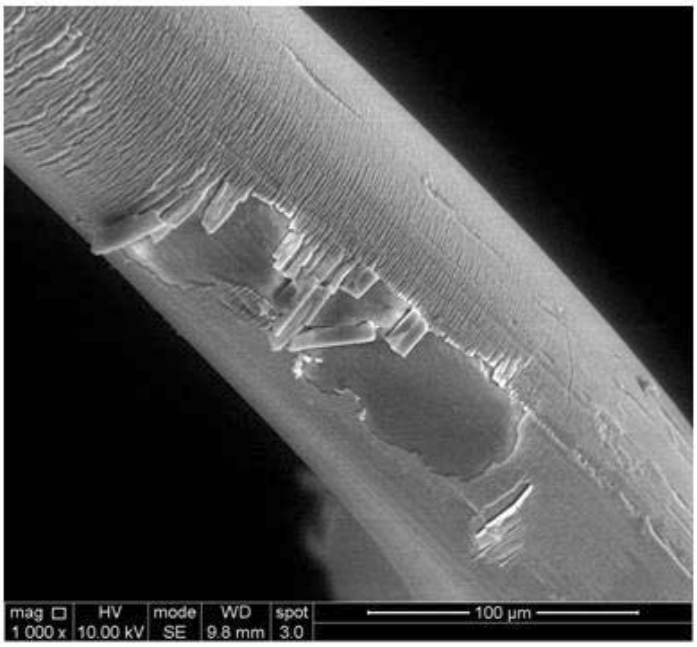

Figure 8 Image of an explant showing areas of visible surface deposit, exposed, uncracked surface underneath and the crust layer peeling off the pristine surface.

The thickness of the layer does not appear to correlate with implant duration in the body (Figure 9) as would be expected for oxidative degradation. In some implants, the layer is characterized by relatively wide bands with parallel edges that appear to have fractured in a brittle manner before peeling from the surface. In other implants, the layer appears to have an "expanded" structure, suggesting the thickness of the layer had more leathery behavior when stretched to create the observed cracks. Still in other explants, no visible crust is observed after more than 5 years of implantation. Variable crust appearance and presence also exists within a single patient explant (Figure 11). For those explants with visible crust, the layer morphology is consistent with the presence of a deposited material and not oxidized polypropylene.

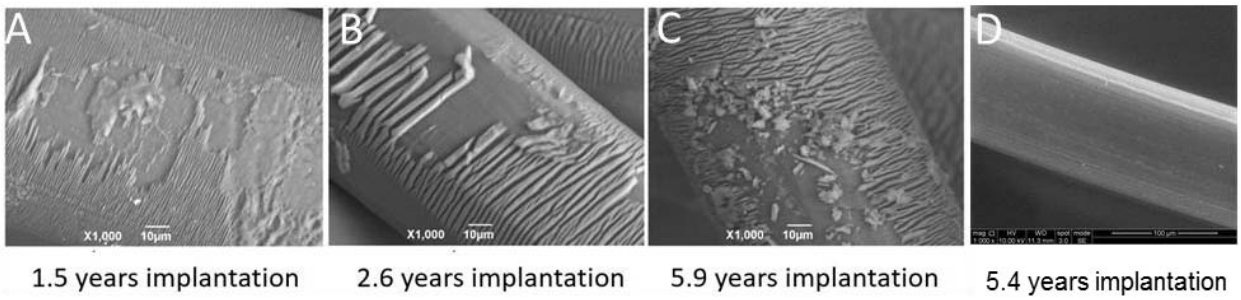

Figure 9 Images of explants from previous reports (A, 1.5 years implanted), (B, 2.6 years implanted), (C, 5.9 years implanted), and (D, 5.4 years implanted). A, B, and C show similar thicknesses of the deposited layer and uncracked fiber underneath. A, B, and C explant images are after all cleaning steps from Wave 3 Minwave 1 cases in the MDL 2187 litigation. D, is after an initial cleaning with bleach and did not have an observable brittle crust, despite its 5.4 years of implantation.

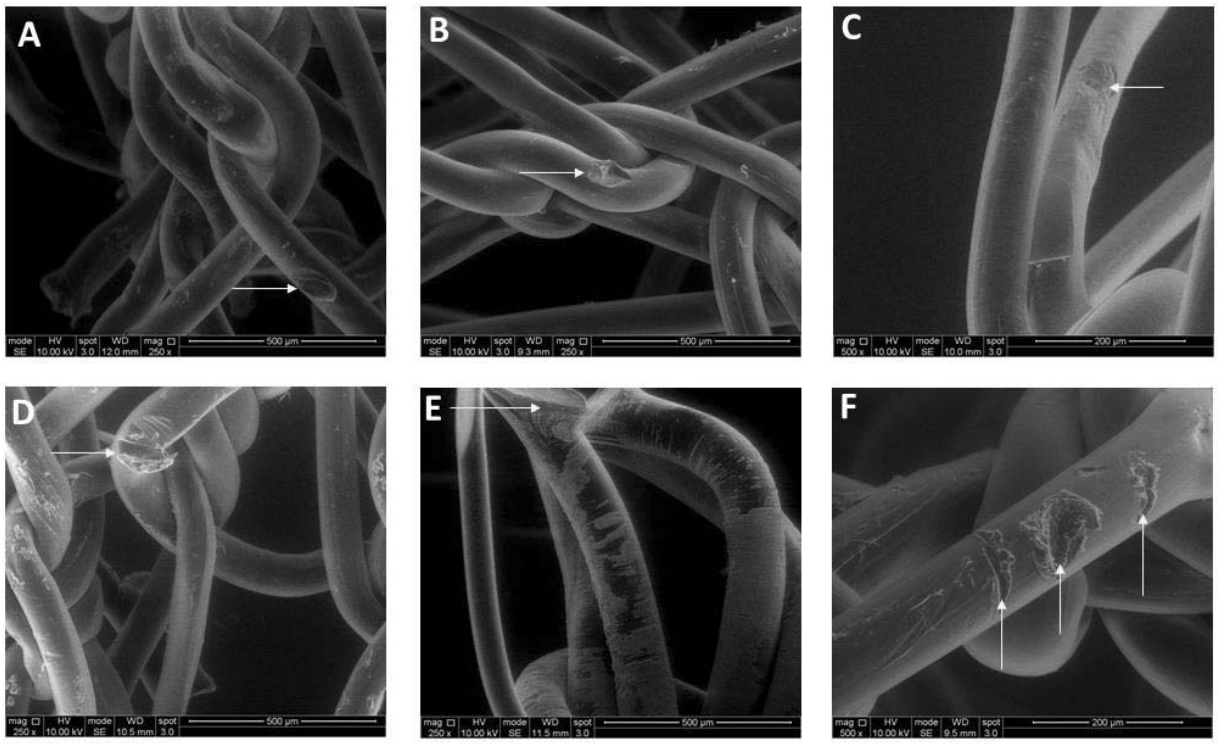

Figure 10 Evidence of ductile mechanical behavior (yellow arrows) in various explants. Images A,B,D,E at 250x. Images C,F at 500x.

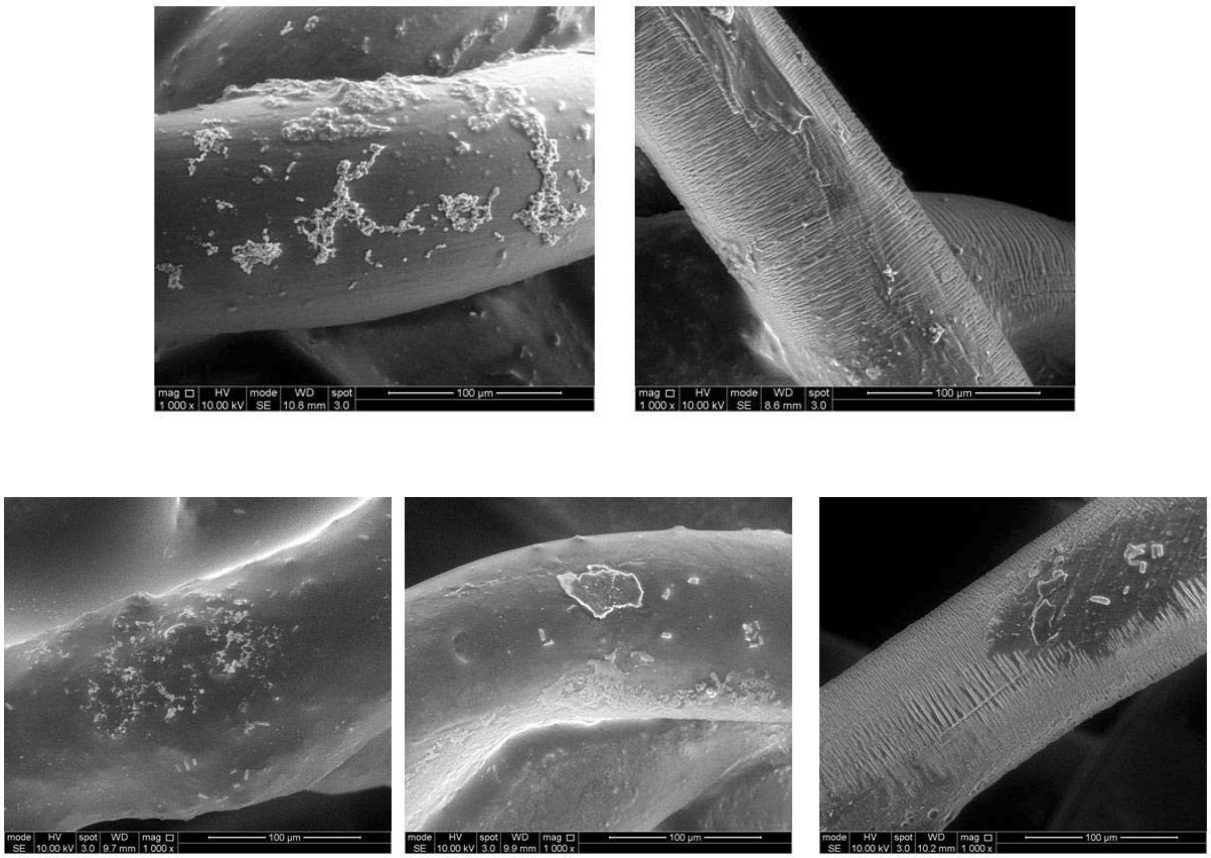

Figure 11 Images of explants showing differences in crust morphology and presence depending on mesh location. Top Row: 4.3 years implantation. Bottom Row: 10 years implantation. (Images were taken after initial bleach soak).

Further confirmation of the defined crust layer was revealed through examination and comparison of cross sectional images created by focused ion beam (FIB) milling followed by SEM imaging of explant and intentionally oxidized (QUV exposed) exemplar materials. Figure 12 is a FIB created cross-sectional comparison of an explant from a previous report with a sample oxidized by seven days QUV exposure (Sample Avaulta 5). Figure 13 is a comparison of an intentionally oxidized sample with an explant, showing the differences in cracking and appearance. Surface and cross-sectional views of the explant and intentionally oxidized exemplar material illustrate differences in typical crack spacing, while cross sectional views illustrate differences in crack depth and morphology. These crack characteristics are markedly different from those observed in the intentionally oxidized exemplar. The explant cross sections

reveal crack morphology that is consistent with presence of an interface between two dissimilar materials where a crack propagating in one material (e.g. the outer crust) would become arrested and/or blunted. Unlike the uniform depth of cracking in the explant, the cracks in the UV exposed fiber are of non-uniform depths and do not show blunting or bifurcation; they remain sharp. These characteristics are consistent with surface-initiated cracks progressing in a material without secondary phases or interfaces. For a more detailed description of the FIB process and an assembly of FIB-related images of exemplar, exemplar oxidized, and explant samples, refer to Appendix AA.

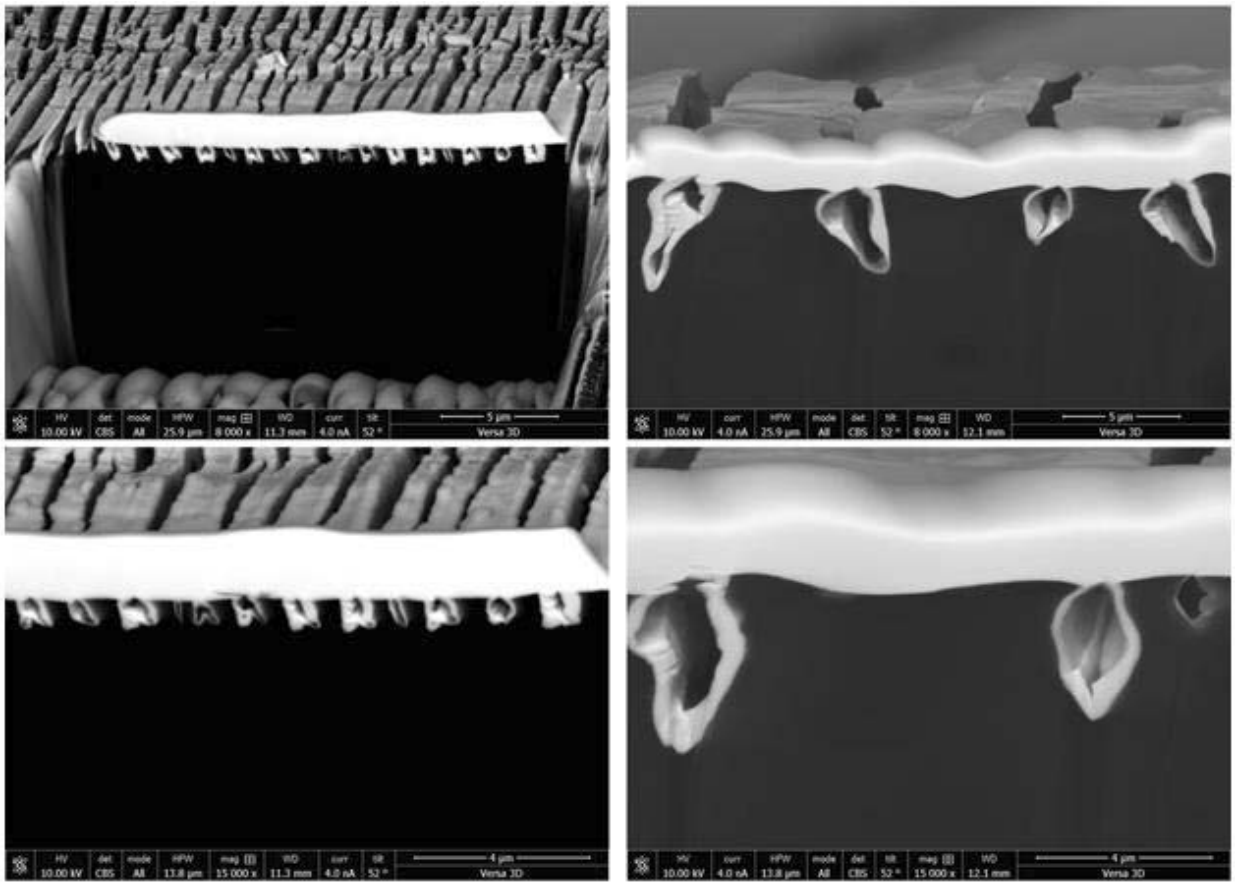

Figure 12 Comparison of cross-section images created using a FIB. The two left images are of an explant from a previous report and the two right images are of a sample intentionally oxidized for 7 days. Paired images have the same magnification.

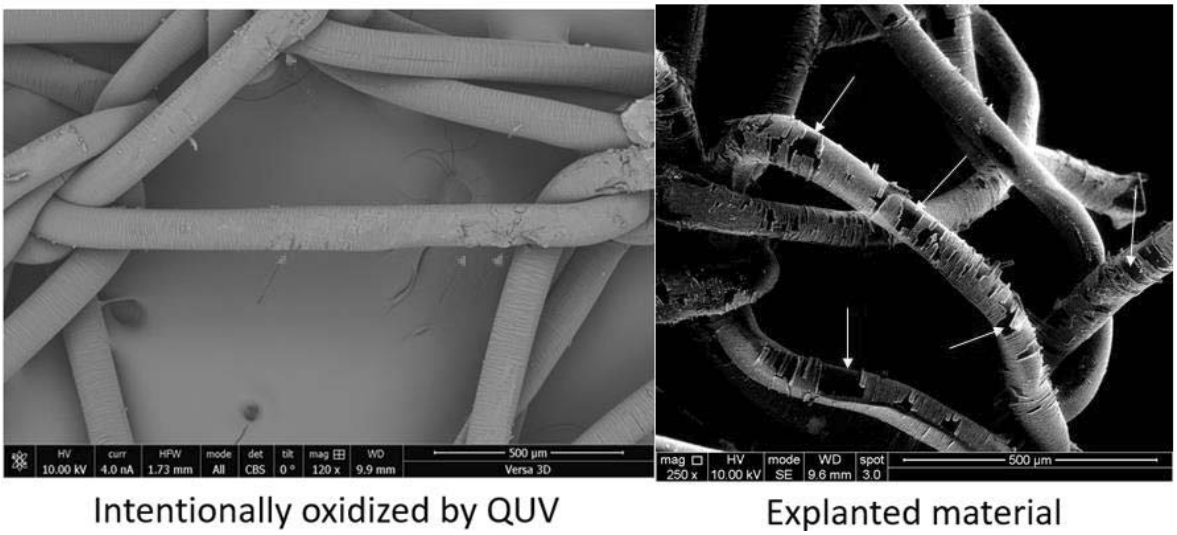

Figure 13. Comparison of intentionally oxidized PP mesh by QUV (left) and an explanted mesh after the 1st cleaning step (right). Red arrows indicate obvious sites of damage associated degradation, which are not present on the explant. Yellow arrows indicate areas where crust is not present, a condition not observed in the oxidized PP.

3.3 Antioxidant Analysis

The stabilizer chemistry present in the polypropylene was assessed using a series of standard separations and analysis methods on the resin pellets.[68] Essentially, the resin was dissolved to free the stabilizers for characterization. The analysis showed that the raw plastic material is formulated by the resin manufacturer to include hindered phenol and phosphite- based stabilizers. Under the conditions of the test, 0.155 wt% stabilizer were detected in the Marlex HGX-030-01. The nature and amount of stabilizers detected is consistent with the testimony of Phillip's corporate witness and confidential documents produced by Phillips related to Marlex

[68] Testing was performed according to K&N lab protocol LC-010, GPC-010, GC-011 & IR-010. Pellets were fully dissolved and the polymer precipitated from solution to allow examination and characterization of the complete additive package.

HGX-030-01 polypropylene.[69] A summary of the data associated with this analysis is provided in Appendix BB.

The primary antioxidant, Irganox 3114, is commonly selected because of its low migratory behavior and effective protection of polyolefins (e.g., polypropylene). The secondary antioxidant, Irgafos 168, is one of the most common secondary antioxidants used in polyolefins. Phillips has also confirmed that "all raw materials used in the manufacture (of Marlex HGX-030-01) meet the standards of the Federal Food, Drug and Cosmetics Act and the rules and regulations promulgated." While they manufactured HGX 0-303-01, Phillips maintained a quality control process and change control process in conformance with FDA regulations and requirements.

The specific additives present in the Marlex HGX-030-01 are commonly used to stabilize polypropylene and have been tested for extractability and toxicity by Phillips (CP-00087-90). However, Phillips does not report having performed specific biocompatibility tests for implantable end products; as expected, they instead ran characterization and tests to affirm production quality and conformance with specified raw material attributes. As repeatedly affirmed by Phillips' corporate witness, the testing specific to an end use and determination of suitability for end use is the responsibility of the resin user, not the resin supplier.[70] The Phillips testimony is consistent with my own experience in selecting and specifying raw materials for an application, my experience in the development of MSDS content, and my work for both a material supplier and for purchasers of materials for various end uses, including implantable medical devices. In this case, Bard performed additional extraction testing to test and verify that any stabilizers or other additives would not be available or able to adversely impact biocompatibility.

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[69] Testing for the presence of stabilizing additives was also previously performed by plaintiffs' experts, who likewise confirmed the presence of the expected Irganox 3114 and Igrafos 168 antioxidants.

[70] Deposition of Frank Zakrzewski, March 7, 2014; pg. 170, ll. 19-pg. 172, ll. 7, pg. 218, ll. 4-9

3.4 Spectroscopic Evaluation

3.4.1 Exemplar Materials

FTIR is a suitable method for assessing the surface of a sample for the presence or absence of chemical functional groups, but is not a direct confirmation of molecular composition. While different techniques, sensitivity, and penetration depths are associated with the various measurements presented by previous Plaintiffs' experts and collected by Exponent, the overall FTIR analyses associated with these products provides an understanding of the chemistry of fiber and explant surfaces. A summary of this data and associated testing conditions is provided in Appendix CC.

Pristine fibers demonstrate the characteristics of isotactic PP homopolymer, and the same spectra as reference pellets of Phillips Marlex HGX-030-01 polypropylene. When exemplar fibers are intentionally oxidized, as described elsewhere in this report, the polypropylene spectrum is altered by the addition of absorbances from carbon-oxygen functional groups and the associated broad absorption band.[71] Over 100 spectra associated with pristine exemplars and exemplars exposed to various chemical and oxidation treatments have been collected and used for comparison and reference purposes in this analysis.

3.4.2 Explanted Materials

Explants, which generally are visually whiter than pristine mesh and exhibit microscopic surface cracking, provide a range of FTIR spectra that generally differ from the underlying PP fiber by the presence of one or more additional functional group resonances. The round and cracked surfaces of explant fibers provide some experimental challenges, but acceptable spectra have been collected via different techniques, including single fiber testing using standard and micro-ATR sampling, and standard ATR sampling of multiple fibers. Many explants exhibit peaks

[71] As described later, the FTIR absorbance is broad and increasing in magnitude with increased exposure time. Within the peak, the greater relative intensity is first seen in the 1710 cm^{-1} region and shifts to higher wavenumbers with increased exposure.

associated with amide bonds (e.g., from proteins), and most exhibit some combination of carbon-oxygen functional groups. Amides and functional groups containing nitrogen in addition to carbon and oxygen are not related to polypropylene or oxidized polypropylene.

Although carbon-oxygen groups are present in oxidized PP (as demonstrated by the data for intentionally oxidized mesh presented later in this report and in Appendix CC), FTIR is not capable of determining if the carbon-oxygen groups in a sample are part of the PP or from another source without additional information.[72] Indeed, previous plaintiffs' experts and the literature have suggested that explanted fibers may have esterified fatty acids, triglycerides, or cholesterol at or on the surface, and we have demonstrated that surface-deposited materials on the polypropylene fibers can contribute carbon-oxygen absorbance peaks to the measured FTIR spectrum.[73] Furthermore, if the FTIR peaks were due to oxidation, one would expect that they would develop in relative intensity over time as oxidation progresses, as demonstrated with the intentionally oxidized mesh. However, increasing oxidative change with increasing implant time is not observed in the explant spectra.

There is no single profile of absorbance peaks associated with explants,[74] no trend in peak development or intensity that correlates with implant time, and no reliable match of explant spectra to spectra of intentionally oxidized reference mesh. However, absorbances associated with carbon-oxygen bonds on the surface of explants decrease with cleaning. The FTIR and associated visual and microscopic observations of explants indicate that the chemistry of the explant surfaces varies by patient and that the surface composition differs from oxidized polypropylene. In light of other available information, including morphology and thermal decomposition behavior, it is more appropriate to describe the surface composition as a non-

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[72] For example, spectra from exemplar fibers were typical of polypropylene, but could be modified to show a carbon-oxygen absorption peak (a sharp peak in the 1730 cm^{-1} region) by the transfer of acrylate-based adhesive to the surface. This peak addition was observed in samples visually exhibiting localized areas of adhesive transfer associated with sample mounting for imaging in the SEM prior to FTIR analysis.

[73] In some historical explant samples a sharp peak is seen near the 1730 cm^{-1} region, which is attributed to the carbon tape used to adhere the mesh samples to mounting stubs for viewing in the SEM.

[74] The varying spectral features, including resonances associated with amides, are also present in FTIR spectra previously collected by plaintiffs' experts

polypropylene deposit. Based on sample history and the observed chemical characteristics (e.g., amides that can be associated with proteins, esters that can be associated with lipids including cholesterol, inorganic elements such as calcium, etc.), this deposit is of biological origin. For a more complete review of FTIR analysis and historical data, refer to Appendix CC.

3.5 Thermal Evaluation

3.5.1 Exemplar Materials

Thermal analysis via DSC and TGA was performed to assess compositional and microstructural aspects of the Bard TVM products. The Marlex HGX-030-01 polypropylene exhibits the expected melting and crystallization behavior of isotactic polypropylene fibers as measured by DSC during heating, cooling and reheating, including the effects normally associated with processing[75] and material lot variability. The collagen layer and blue fiber were also evaluated for melting, crystallization and other thermal events. The behavior of each material was unremarkable and consistent with expectations for each materials type.

Heating well above the melting and processing temperatures, particularly in oxygen, leads to eventual decomposition and weight loss, which can be measured by TGA. Clear Marlex HGX-030-01 polypropylene decomposes completely in TGA testing, leaving essentially no non-combusted residue at the end of the test.[76] Blue fibers tested in this way decomposed in a similar manner, but a residue consistent with the copper phthalocyanine pigment used to create the blue color is observed in the sample pan. The protein-based collagen, which is a fully opaque white sheet of material, forms a char or residue after decomposition.

Thermal analysis by DSC reveals differences in melting peaks and the energy of melting between exemplar materials and explants, and observed variability amongst explants. The differences are likely related to normal annealing and aging due to exposure to body

[75] For example, the fiber geometry as well as the type and degree of crystallinity developed during fiber drawing and heat setting can contribute to changes in peak shape and position during melting.

[76] Polypropylene is not a char-forming polymer under these test conditions.

temperature and may also be related to the constraining effect of the crust during melting. The observed differences are not confirmation of degradation or a defective change in the material. For example, if the material were degraded, crystallization would be expected to occur at higher temperatures than is observed. Furthermore, the presence of a foreign material typically affects heat flow measurements in DSC and this appears to be the case with explanted samples. Available DSC data does not support the assertion that polypropylene in explants is degraded. To the extent that GPC data has been presented and interpreted to show a loss of molecular weight in implants compared to non-implanted mesh, I note that the data fails to account for lot-to-lot variability in molecular weight, incorrectly analyzes data that is consistent with the presence of a second material, and improperly includes a different flow grade of polypropylene from a different manufacturer as a reference. For at least these reasons, the GPC data does not provide evidence of loss of molecular weight due to oxidation.

TGA testing provides important insights into the composition of the explanted mesh. As noted above, the clear Marlex HGX-030-01 polypropylene in Bard TVM products decomposes completely during TGA analysis; however, this full decomposition is not observed in explants. Although the main decomposition profiles mimic exemplar materials, a shriveled film-like residue remains in the pan after TGA testing of explants. The amount of the residue varies between explants and is less commonly observed the more the cleaning process removes the crust, but is distinct from the residue associated with blue fibers or the collagen layer, the effect of residual carbon tape from prior SEM imaging, and the scratches or haze sometimes associated with the pans after use. When viewed in the SEM, the residue is three-dimensional and contains some inorganic components (e.g., calcium, phosphorous and other elements that are found in the body) not associated with the HGX-030-01 polypropylene. As explained in a later section, this residue is not consistent with oxidized polypropylene. The residue is consistent with the presence of a layer of material of biological origin deposited on the filament surfaces and adhered sufficiently to resist standard cleaning methods. Furthermore, comparison of the decomposition profiles for exemplar, explant and intentionally oxidized mesh demonstrate that the explant material is consistent with exemplar polypropylene and not the shifted profile due to degradation observed when mesh is intentionally oxidized. A summary of the thermal analysis data is provided in Appendix DD.

3.6 Resistance to Chemical and Forced Oxidative Degradation

3.6.1 Oxidative Induction Time for Exemplar Materials

Stabilizer effectiveness was assessed during forced degradation testing, including TGA and oxidation induction time (OIT), of pellets, greige goods, and mesh products. When heating profiles, test duration, and oxygen concentrations are sufficiently intense, the stabilizers are depleted and the polypropylene oxidizes, generating a measureable heat of reaction and a visible change in the appearance of the material. Testing demonstrates the antioxidant activity and effectiveness of the stabilizers in the formulation, including protection of the polypropylene in the finished product. For example, there is no measurable oxidation for over 16 hours at 160°C in pure oxygen. There is no evidence of excessive loss of stabilizer from processing.

The resistance to oxidation observed in OIT testing provides a measure of the antioxidant protection in the material. The OIT testing confirms that Bard TVM meshes made from HGX-030-01 are well stabilized against oxidation, and not reasonably expected to suffer from oxidation during use. This testing addresses the potential for initiation of oxidation during processing, as sometimes alleged by Plaintiffs, and shows that the temperatures and conditions of materials conversion (e.g. extrusion, knitting and heat setting) and device manufacture (e.g., sterilization) do not lead to degradation of the mesh during the expected lifetime of the product. This testing also demonstrates the durability of the mesh in the face of a highly oxidizing environment that is more challenging to the material than would be encountered in use. Data associated with OIT testing is summarized in Appendix EE.

3.6.2 Chemical Exposure of Exemplar Materials

Plaintiffs assert that the mesh is chemically degraded via oxidation when implanted in the body. To test this hypothesis, Exponent subjected exemplar samples to various potential oxidizing agents including 10% sodium hydroxide (NaOH), 3% and 30% hydrogen peroxide (H_2O_2), 10-15% sodium hypochlorite (bleach), 5% iodine in water, 10 % betadine and 6M hydrochloric acid (HCl) at ambient and elevated temperatures. Exposure to these chemicals was accelerated (e.g., in duration, concentration, temperature, etc.) compared to any reasonable biological condition, and was designed to produce an oxidative response of the polypropylene. Two

solutions were specifically selected to intentionally induce oxidative degradation in an accelerated fashion based on publicly available literature: immersion in the 10% NaOH (pH 13) at 50°C[77] and immersion in a cobalt (II) chloride buffered 30% hydrogen peroxide at 37ºC.[78] When evaluated visually and by FTIR after this testing, little or no alteration of the appearance or surface chemistry of the mesh was observed, and no sample exhibited the cracked surface morphology of an explant. Particularly noteworthy is the observation that aggressive peroxide exposure failed to induce oxidation or a morphology similar to that observed in explants. Images and a summary of data associated with chemical exposure testing are provided in Appendix FF.

3.6.3 Exposure of Exemplar Mesh to QUV Testing

Exponent was able to force the oxidation and surface degradation of Bard TVM products by exposure to intense photo-oxidative challenge at elevated temperature. While UV oxidation is not an expected nor realistic mechanism for mesh degradation within the body, this testing produced materials with known composition and history that could be used for experimental controls and comparison of explant materials to polypropylene mesh known to be oxidized.

Exemplar materials were subjected to QUV testing, a combination of elevated temperature and ultra-violet (UV) radiation, using a UVA 340 bulb. Several exposure studies were conducted, including under dry, continuous exposure for up to 10 days, irradiance up to 0.89 W/m^2, temperatures up to 60ºC, with and without imposed loads. After sufficient time, fibers were measurably oxidized visually (Figure 14) and as indicated by a distinct broad peak in FTIR (Figure 16). The broad FTIR oxidation peak increases in magnitude with increased exposure time. Within the peak, the greater relative intensity of the apparent subpeak first seen in the 1710 cm^{-1} region shifts to higher wavenumbers with increased exposure as different types of carbon-oxygen groups develop (e.g., acids, ketones, aldehydes, esters). Cracking appeared

[77] These conditions were selected based on PP oxidative damage images in the text Ehrenstein, G., et al. (2011). SEM of plastics failure. Munich, Germany, Carl Hanser Verlag.

[78] Conditions were selected based on oxidative damage studies of implantable polyurethanes such as those found in Christenson et al (2005), which was 20% hydrogen peroxide solution at 37C.

sooner in samples under load, and penetrated to varying depths within the fiber. When portions of the oxidized surface were broken some penetrating cracks were still visible on the underlying surface. Notably, the FTIR peak associated with oxidation was clearly present when the surface was minimally cracked, a condition that is dissimilar to the explants.

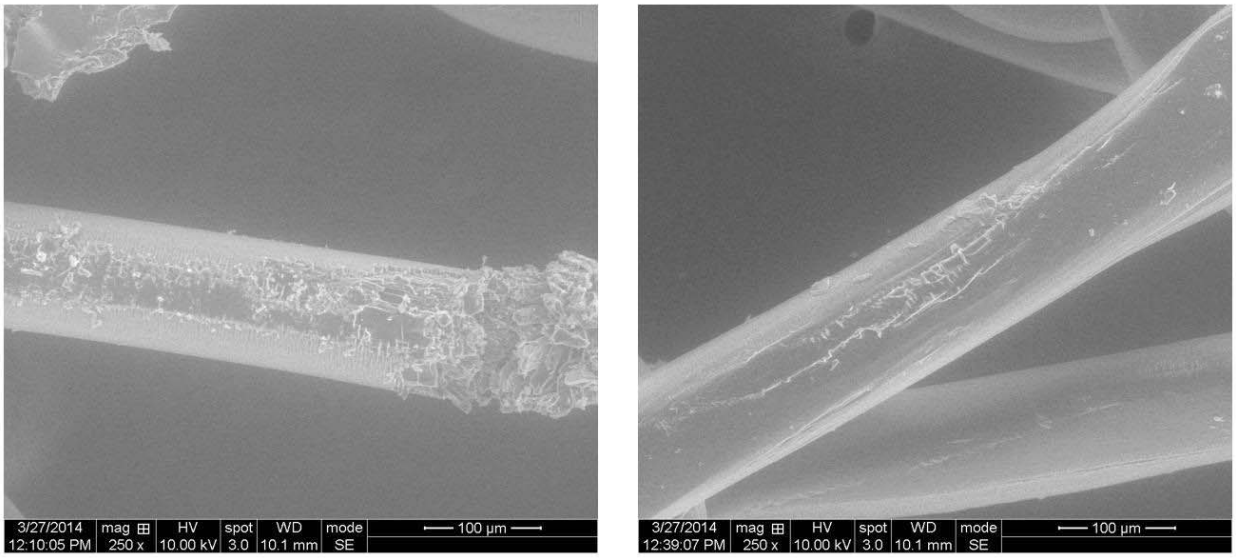

Figure 14. SEM Images of intentionally oxidized exemplar mesh irradiated at 0.89 W/m^2 at 60°C after 3 days with (left) with a 1 lb load attached and (right) with no attached load. After three days with load, numerous cracks can be seen as well as signs of major degradation. Cracking is observed with no load, although in less amount.

Qualitatively, cracking intensity and average crack depth also increased with exposure time. For more extensively oxidized materials, crack depth varied throughout the material providing a structure dissimilar to that of the crust layer found on explanted materials (Figure 17). Cracking from oxidation corresponded to a loss of mechanical strength, which can be observed when handling the samples, and was demonstrated by samples placed under 1 lb of load that fractured after approximately three days of QUV exposure. Notably, no core/shell or layer structure similar to explanted mesh morphology was observed in the QUV samples via fracture analysis or FIB cross sectioning, and as reported previously, no mechanical failure has been reported for the explants. Further, surface cracking intensified when intentionally oxidized samples were progressively cleaned in the same manner as explants (i.e., the combined action of sequential sonication and soaking in DI water, NaOCl, and Proteinase K). This is in direct contrast to the

behavior of explants, where cleaning reveals the original fiber underneath. Figure 15 below is a comparison of the intentionally oxidized samples before and after cleaning, with that of an explant, before and after cleaning. Additionally, the cleaning solutions, post-cleaning, were tested by GC-MS and did not identify molecules indicative of PP degradation, refer to Appendix GG.

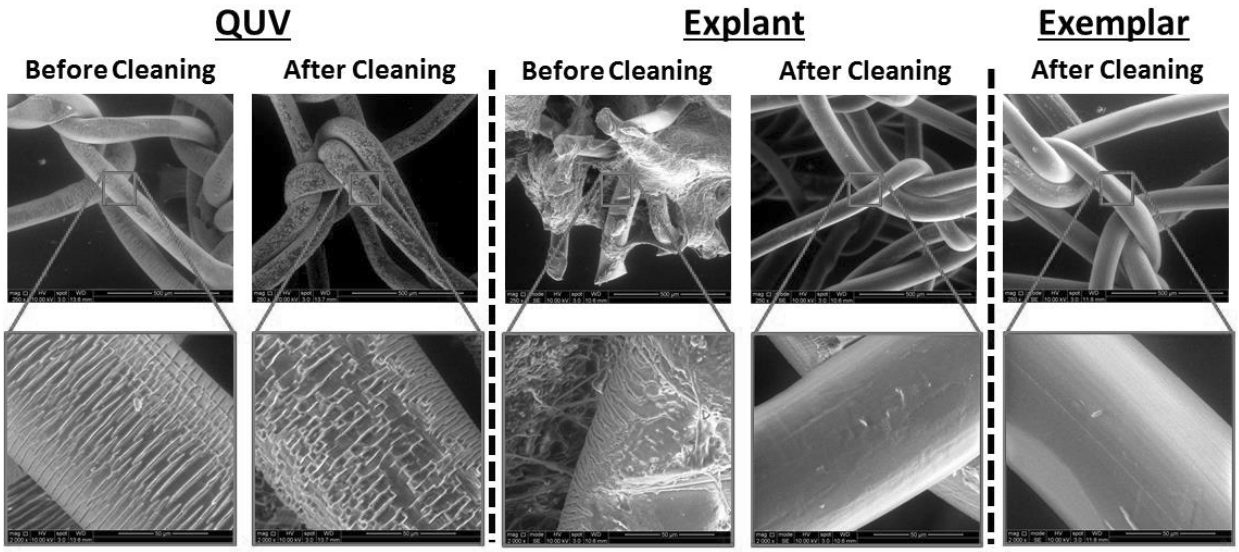

Figure 15. SEM images of before and after the full cleaning procedure of (left) an intentionally oxidized exemplar mesh, (middle) an explanted mesh (previous report), and (right) a pristine exemplar. Cleaning intensifies cracking in an oxidized fiber, but cleaning the explant reveals smooth fiber similar to the exemplar.

This testing demonstrated that the combination of appearance, mechanical properties, and broad FTIR absorbance around 1735 cm^{-1} that result from oxidation of the Marlex HGX-030-01 PP was different than the combination of appearance, mechanical properties and assorted FTIR absorbance exhibited by explants.

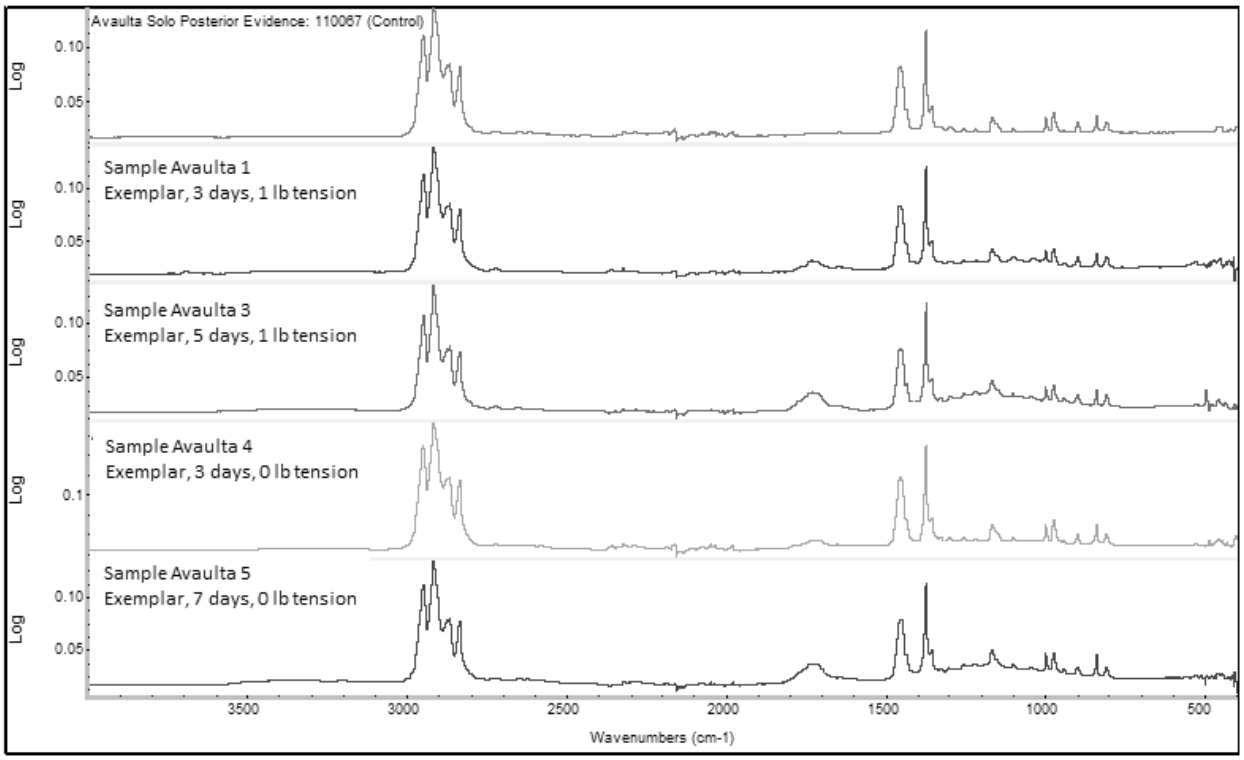

Figure 16 Comparison of intentionally oxidized samples from QUV radiation with an exemplar material. Observation times and load conditions are noted in legend. Sample Avaulta 3 fractured after day 3, and was removed from QUV testing by day 5.

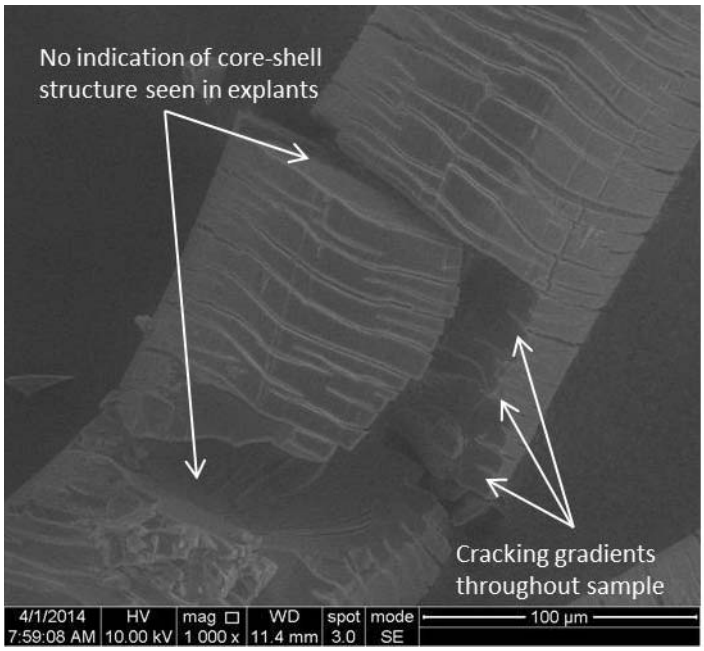

Figure 17 SEM image of exemplar mesh after 10 days QUV irradiation of 0.89 W/m2 at 60°C

Thermal analysis also showed distinct differences resulting from oxidation. This included the loss of high melting point crystals and the development of crystals with additional melting points more than 10°C lower as measured by DSC, as well as notably different decomposition behavior in TGA (Figure 18). When pristine, cleaned and oxidized controls from the same lot are compared, the shift to lower decomposition onset is readily observed, which is consistent with the expected loss of molecular weight from oxidation. Figure 19 compares our controlled data with literature data. Clearly, the explant peak shifts in the opposite direction of the oxidized material. Additionally, like exemplar polypropylene and unlike the explants, the oxidized sample did not leave a residue after TGA testing. This data provides objective comparative data that contradicts Plaintiffs' hypothesis that the Marlex HGX-030-01 polypropylene in Bard TVM meshes oxidizes and degrades to a brittle crust in use. It supports other data that indicates that the morphology of explant surfaces is associated with a deposited layer and not the oxidation of polypropylene. For a more complete review of the QUV exposure, refer to Appendix GG.

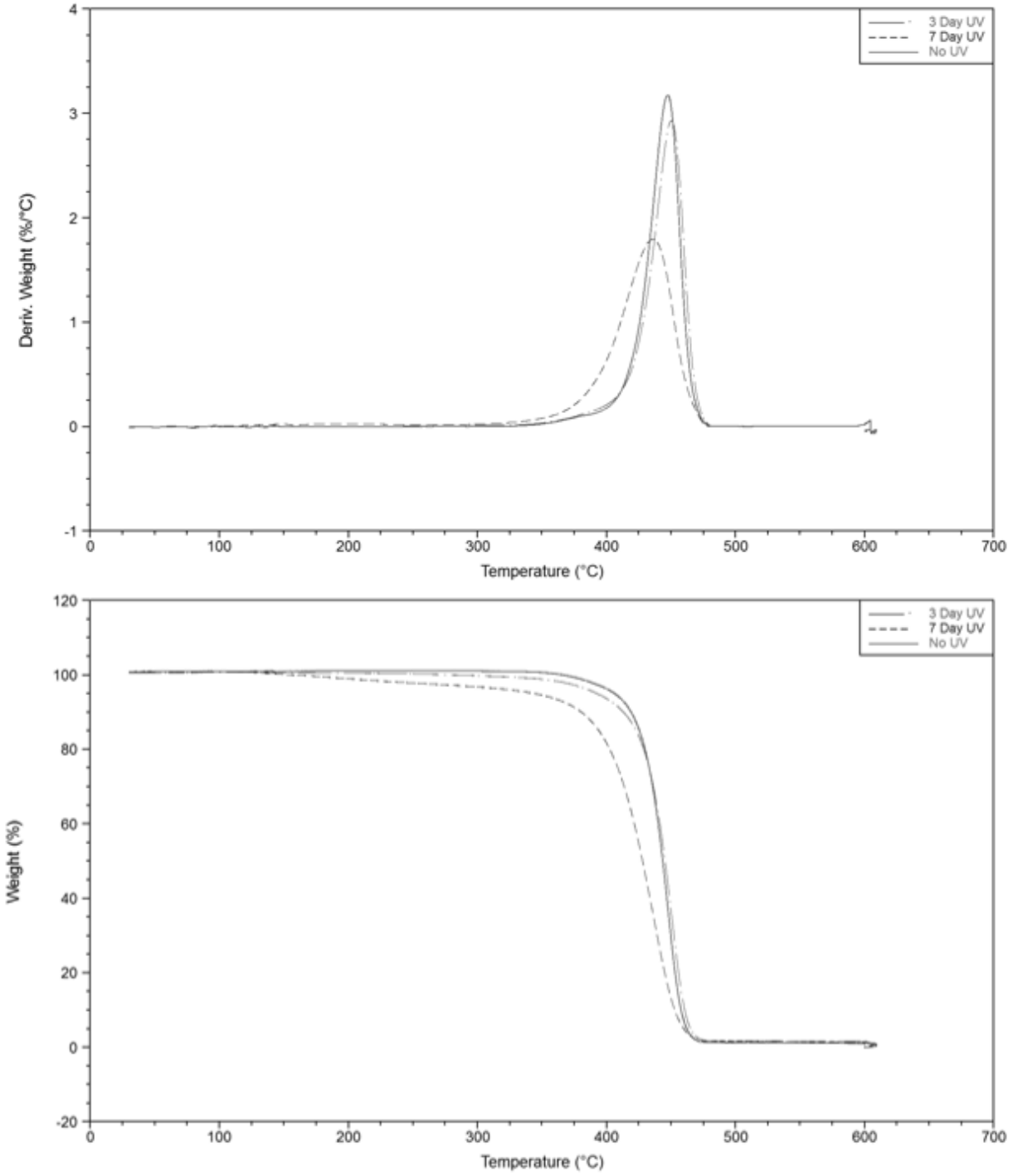

Figure 18 TGA comparison of intentionally oxidized samples by QUV irradiation with exemplar materials. (Top) Weight Change vs Temperature, (bottom) Weight Percent Loss vs Temperature

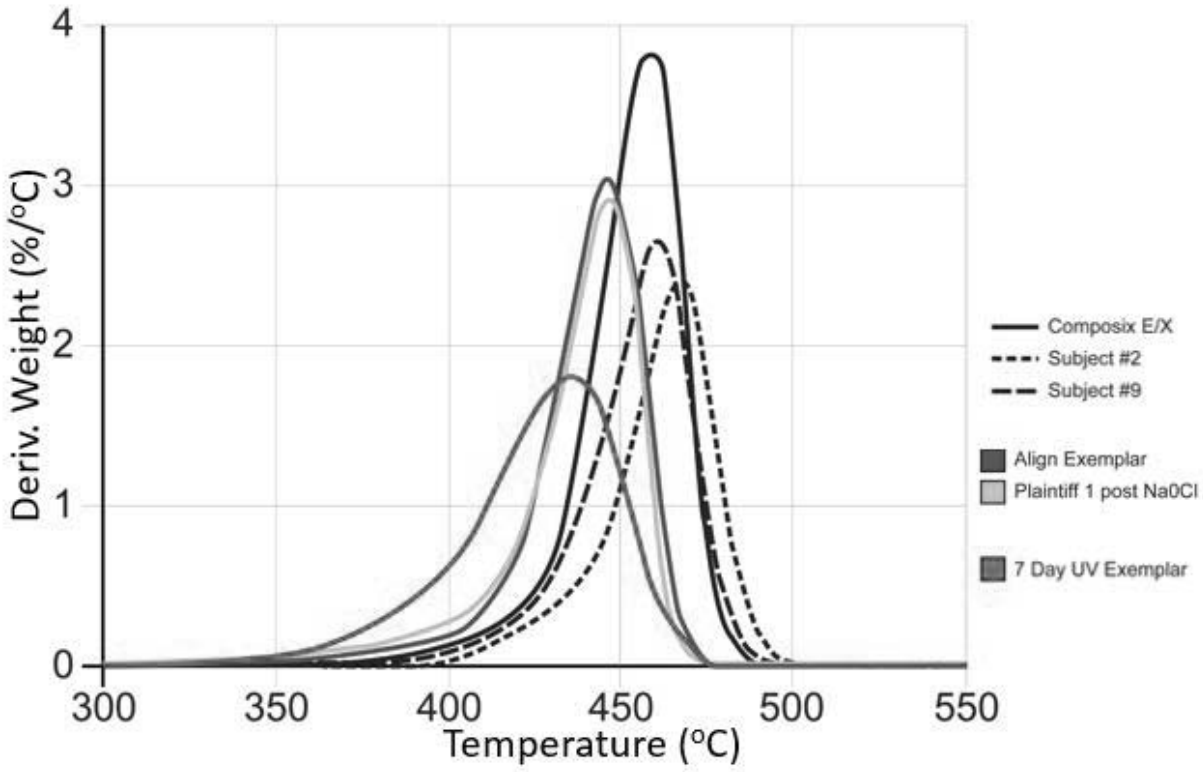

Figure 19. TGA derivative plots comparing literature[79] data and Exponent's data with intentionally oxidized samples

Based on the data and observations associated with the Marlex HGX-030-01 polypropylene in Bard TVM mesh materials, including repeated assessments of microscopic condition and morphology, as well as testing by FTIR, DSC, OIT, TGA, EDS, stabilizer chemistry assessment, and resistance to thermal, radiation and chemical oxidation, these materials are stable under conditions of intended use and do not exhibit evidence of oxidative degradation due to manufacturing. There is no evidence of material changes that would alter the biocompatibility or performance of the material from that assessed during qualification and use of this polypropylene and the Avaulta and Align products.

[79] Costello, C. R., S. L. Bachman, S. A. Grant, D. S. Cleveland, T. S. Loy and B. J. Ramshaw (2007). "Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient." Surg Innov 14(3): 168-176.

4 General Response to Previous Plaintiffs' Testing and Opinions Related to Bard's TVM Products

Previous Plaintiffs' experts have reported that some portion of explanted polypropylene meshes exhibit a brittle surface texture that includes predominantly circumferential cracking and assert that this texture is evidence of oxidation. However, direct examination and testing of explanted Bard TVM products and comparison to as-manufactured, intentionally oxidized and chemically challenged exemplar mesh, as well as review of related data from other sources, does not support Plaintiffs' hypothesis of oxidative degradation of the polypropylene of the TVM products in the body.

Plaintiffs experts have also previously suggested that the observed cracking is due to environmental stress cracking (ESC) from exposure to lipids such as cholesterol. ESC results from the combined action of stress and a chemical with marginal compatibility such that local plasticization and local advancement of crack fronts occur. Notably, the polymer itself is not chemically altered in ESC, so assertions of oxidation and molecular degradation are inconsistent with this mechanism. ESC cracking will occur everywhere that sufficient stress and chemical exposure is encountered, and more aggressive local combinations will lead to preferential crack advancement. As a general matter, polypropylene is recognized for ESC resistance, and compatibility with lipids. The location and extent of cracking on explants is inconsistent with the exposure and stress profile expected for implanted mesh, indicating ESC is not the cracking mechanism. Additionally, cross-sectional images from the FIB showing the blunted cracking indicative of a defined brittle layer on the fiber surface are strong evidence that ESC is not a factor in the cracking seen with the explants (Figure 12).

While a brittle surface is visible on some portion of the subject explanted polypropylene meshes, it is not from polypropylene oxidation of from ESC. Previous Plaintiffs' experts' data can be reasonably explained by the presence of a surface deposit (e.g., a biofilm) that is more brittle than the polypropylene filaments, rather than the development of a brittle filament surface due to oxidation of the polypropylene. The presence of deposited biofilm is supported by data, such as non-combustible residues and chemical signatures distinct from those of polypropylene

or oxidized polypropylene as well as qualitative observations of surface and cross sectional appearance, crack morphology and crack depth, and mechanical properties. The presence of deposited biofilm is also consistent with expected biological processes in which proteins and cells adsorb to implanted surfaces. Thus, previous plaintiffs' experts have not provided a reasonable scientific basis for their assertion that the polypropylene is oxidized *in vivo*, or that the alleged oxidation is associated with adverse clinical outcomes. It is my opinion to a reasonable degree of scientific and engineering certainty and/ or probability that the cracked surface is actually a layer of a material of biological origin, and not the alleged oxidized polypropylene.

Plaintiffs' experts have essentially advanced the position that clinical complaints are because of the incompatibility of polypropylene mesh, which previous Plaintiffs' experts have stated is the result of oxidation of the polypropylene. Specifically, they assert that the Bard TVM products exhibited *in vivo* oxidative degradation, that polypropylene is not inert, and that oxidative degradation led to a reduction in molecular weight of the polypropylene, which in turn caused a reduction in mechanical properties. Plaintiffs' experts have also suggested that the information reflected in the Bard's 510k regulatory documentation related to the physical characteristics of the mesh products demonstrates the products were defectively designed. As I have outlined elsewhere and explained further here, those opinions are without reasonable scientific support.

4.1 Marlex HGX 030-01 polypropylene is a reasonable and stable biomaterial

Plaintiffs' experts have suggested that the Phillips Marlex HGX-030-01 polypropylene used in the Bard TVM products is a defective material that is not biocompatible or suitable as an implantable biomaterial. I disagree. I have provided a basis for my opinion here and in the analyses outlined elsewhere in my report.

Polypropylene including Marlex HGX-030-01 is a recognized biocompatible material, with a decades-long history of successful clinical use. This history is complemented by Bard's research and analysis related to implantable polypropylene mesh, and Bard's direct history of testing and use of Marlex polypropylene homopolymer since the 1960s.

4.1.1 MSDS language does not mean the material is incompatible or unsuitable for use in humans as part of qualified, finished implantable medical products.

A standard form of communication about raw materials is through data sheets, including the Material Safety Data Sheet (MSDS) and Technical Data Sheet (TDS). These commonly are written to apply to more than one grade of a resin, and therefore may contain information that is not specific to each grade covered. They are intended to provide general information, and are not a substitute for specific analysis to be defined and performed by the purchasers of the resin in light of their intended use. For example, the 2004 MSDS for Marlex HGX-030-01 states "information provided herein relates only to the specific product designated and may not be valid where such product is used in combination with any other materials or in any process" (CP00041). The data sheets also include disclaimers with language such as "[b]efore using this product, the user is advised and cautioned to make its own determination and assessment of the safety and suitability of the product for the specific use in question and further advised against relying on the information contained herein as it may relate to any specific use or application" (CP-00016).

While a later MSDS for Marlex HGX-030-01cautions about implanting the material in the human body, nowhere does it state that the material would do harm if it were implanted. In fact, Phillips "makes no representation, promise, express warranty or implied warranty concerning the suitability of this material for use in the human body or in contact with internal body fluids or tissues" (CP-00087-90). As indicated earlier, "medical grade" is a market designation, not an industry-standard term, and it means different things to different raw material suppliers and purchasers. It does not assure a material will perform or fail to perform in a medical application. Furthermore, raw material supplier information is subordinate to testing and evaluation related to a finished medical device. Bard appropriately assessed biocompatibility and function and reported its findings and experience to the FDA in the manner of a reasonable medical device manufacturer.

A Material Safety Data Sheet or MSDS is not a biocompatibility document. It is an industrial communication related to occupational exposure to raw materials. The MSDS does not pertain to finished products that will be implanted in the body, and does not address testing,

characterization, or assessment of suitability for specific applications. Phillips' testimony confirms that suitability is to be determined by the end user. This is consistent with the intent of the Biomaterials Access Assurance Act of 1998, which was enacted to encourage material suppliers to continue to sell to medical device manufacturers.[80]

In this case, Bard demonstrated the biocompatibility of its TVM products through a multitude of cellular and animal tests in accordance with ISO 10993. This is consistent with the expectations expressed in sworn deposition testimony by Phillips' designated corporate witness in regards to material and product testing.[81] The biocompatibility of the Bard TVM products also builds on the efficacious clinical history of polypropylene and animal-based collagen as materials for surgical meshes, including uses for vaginal tissue repair, and for other medical products (e.g. surgical sutures), Bard's own experience with related and predicate products, and its core material set (e.g. Phillips HGX-030-01, Collamend collagen). The Bard TVM products are made from materials that have been well characterized chemically and physically and have a long history of safe use. The biocompatibility of the component materials of the Bard TVM products has been established in that the predicate products (including those manufactured by Bard) include the same materials, manufacturing, sterilization, and tissue contact profiles.

Plaintiffs' experts previously claimed that Marlex polypropylene was "incompatible" with oxygen and oxidizing agents when, in fact, the MSDS merely states that polypropylene "may react with oxygen and strong oxidizing agents, such as chlorates, nitrates, peroxides, etc" (CP-00047). Nearly all materials react with oxygen and strong oxidizing agents under certain conditions. However, common compatibility charts indicate polypropylene is actually resistant to many chemical oxidants like chromic acid, hydrogen peroxide, and potassium permanganate that produce conditions much harsher than those observed in the human body. More importantly, direct testing of exemplars demonstrates that the Bard TVM products resist

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[80] In the wake of certain high profile medical device litigation, many raw material suppliers took steps to minimize sales of their materials into medical device applications, especially for implantable devices. The act was a response to concerns about raw material availability and its impact on innovation and access to medical devices.

[81] Deposition of Frank Zakrzewski, dated March 7, 2014, with exhibits 1-26

oxidizing conditions more aggressive than would be expected in the body, while direct testing of explants demonstrates that this polypropylene is not oxidized during use.

There are certain conditions under which polypropylene can oxidize, but these are not the conditions encountered by Bard's TVM products. Phillips' designated witness was unaware if the potential oxidizing reactions listed on the MSDS would occur in finished medical devices in the human body.[82] I have not seen data that scientifically supports these statements, either. In contrast, there is substantial data in the literature and Bard documents supporting the medical use of Marlex polypropylene and use of Marlex HGX-030-01 polypropylene in implants that contradicts the data sheet statement.[83] Indeed, mesh manufactured by Bard from Marlex polypropylene resin has been implanted safely in millions of patients for over four decades.[84] Furthermore, I have investigated this by evaluating explants and performing challenge testing with strong oxidizers, including peroxide solution and concentrated mineral acids, and found that they do not degrade via oxidation *in vivo*. Thus, oxidative degradation *in vivo* is not a foreseeable risk for the Bard TVM products.

4.1.2 Literature references to the potential for polypropylene oxidation do not provide specific scientific support for the hypothesis that the Plaintiffs' meshes are oxidized *in vivo*

Publications have identified a cracked surface on explanted polypropylene mesh and suggest that the cause is oxidation of polypropylene, although the limited associated compositional analysis has been inconclusive (Costello, Bachman et al. 2007, Costello, Bachman et al. 2007, Clave, Yahi et al. 2010, Cozad, Grant et al. 2010, Ostergard 2011, Sternschuss, Ostergard et al. 2012, Iakovlev et al. 2015, Imel et al. 2015, Talley et al. 2017). These publications principally rely on the visual observation of a cracked surface morphology and do not provide conclusive evidence that polypropylene meshes undergo oxidation *in vivo*. Furthermore, allegations of *in*

[82] Deposition of Frank Zakrzewski, dated March 7, 2014, with exhibits 1-26

[83] Boston Scientific also assessed the biocompatibility of Marlex HGX-03-01 in its Pinnacle device. It provided the MSDS as part of its regulatory filing, responded to related questions from the FDA after discussions with Phillips, and received clearance for the product.

[84] Deposition of Roger Darois, dated June 19, 2013, at pp. 40-41

vivo oxidation are based on theories of reactive oxygen species (ROS) causing oxidative degradation of fiber surfaces. However, *in vitro* studies with supra-physiological conditions of ROS have not produced physical surface features that replicate surface features found on explants (Figure 20). When oxidation is forced by UV exposure, brittle cracking can generally be created but does not share key aspects of explant morphology, indicating the UV-based cracking is of a different origin than the crust cracking (Figure 12, Figure 13, Figure 15, Figure 20).

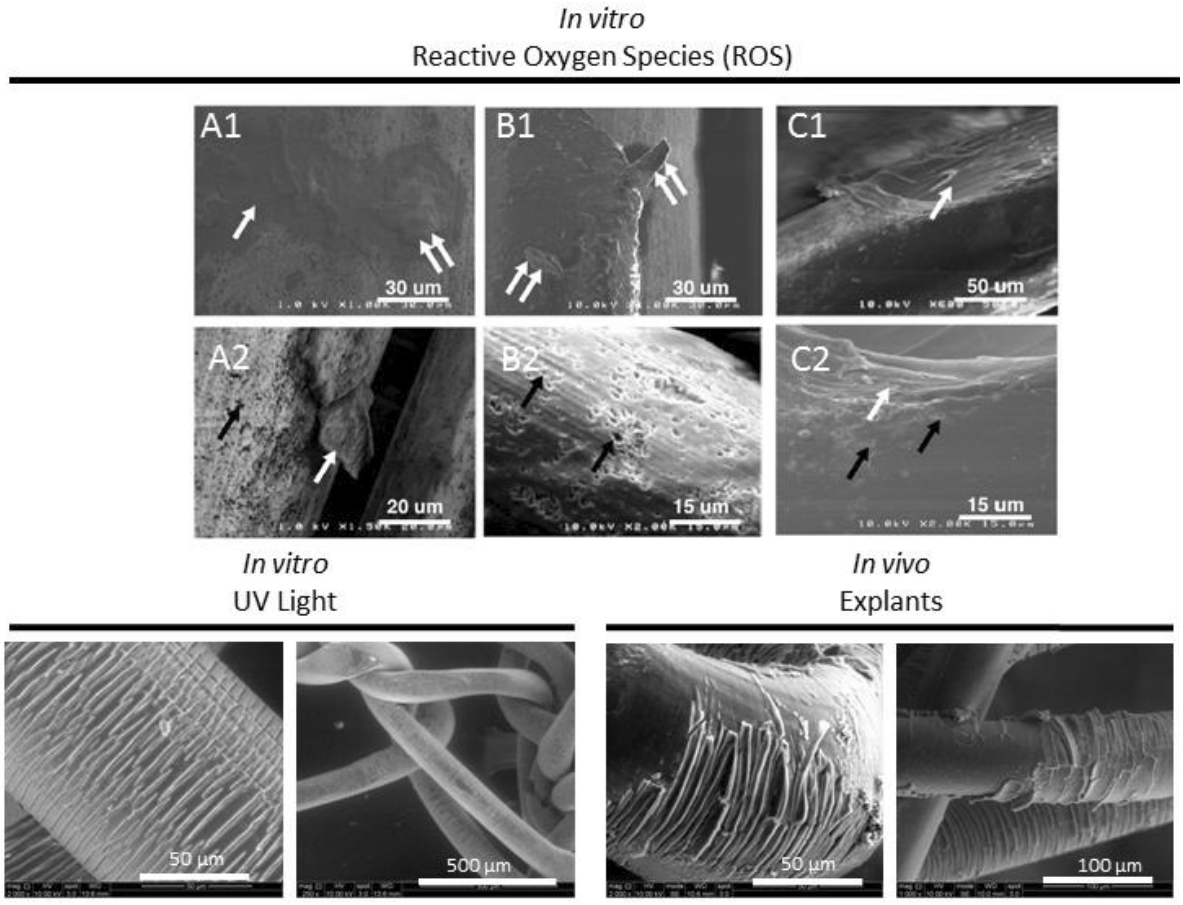

Figure 20. SEM images of surface features of polypropylene mesh after forced oxidation through ROS or UV light in comparison to surface features on explants. Top Row: SEM images obtained after immersion in 20 wt% H_2O_2 for 5 weeks at 37°C. Devices: A – TVT, B – Advantage, C – Lynx. Bottom Row: (left) SEM images obtained after 10 days of UV light exposure at elevated temperature (60°C). Bottom Row: (right) Images of explants. Top Row (*in vitro ROS*) images adapted from Talley et al. (2015).

The discrete nature of the cracking layer observed on explants supports its association with a deposited coating or crust, rather than the gradient of embrittlement, varying crack depth, and the cracking features that are typically observed with oxidation. Oxidation occurs progressively inward from the surface. Notably, the surface of the explants has a distinct layer that can be mechanically removed, or gradually decomposed by appropriate cleaning solutions (Figure 4). Such a shell/core characteristic is not associated with oxidation.

A study published by De Tayrac and Letouzey (De Tayrac 2001), showed that surface features similar to those on the explants could be created by the intentional deposit of a brittle biofilm (Figure 3). In the study, the biofilm was created through infection, though the same principles would apply to any coating of similar mechanical properties. This deposited biofilm exhibited cracking and a general surface appearance similar to that identified by previous Plaintiffs' experts as possibly indicating oxidation. The authors were able to combine sonication with a solvent to remove the biofilm and reveal the undamaged fiber beneath it (de Tayrac and Letouzey 2011). Another study (Thames, White et al. 2017) focused specifically on transvaginal mesh explanted from numerous individuals. The Thames analysis showed polypropylene meshes did not degrade *in vivo,* but rather were coated in a biologic crust that was sepcifically adherent due to the formalin fixative process.

Exponent demonstrated a similar principal by soaking exemplar mesh in human serum for 7 days and allowing it to dry to a coating. The deposited film fractured in a brittle fashion when the fibers were flexed revealing the pristine fiber beneath the crust (Figure 21).[85]

[85] The cracking pattern in this demonstration is different than that of an explanted mesh, for reasons likely related to specific exposure conditions, duration, fixation and specific mechanical forces. However, the principle of a composite structure and associated behavior is the same.

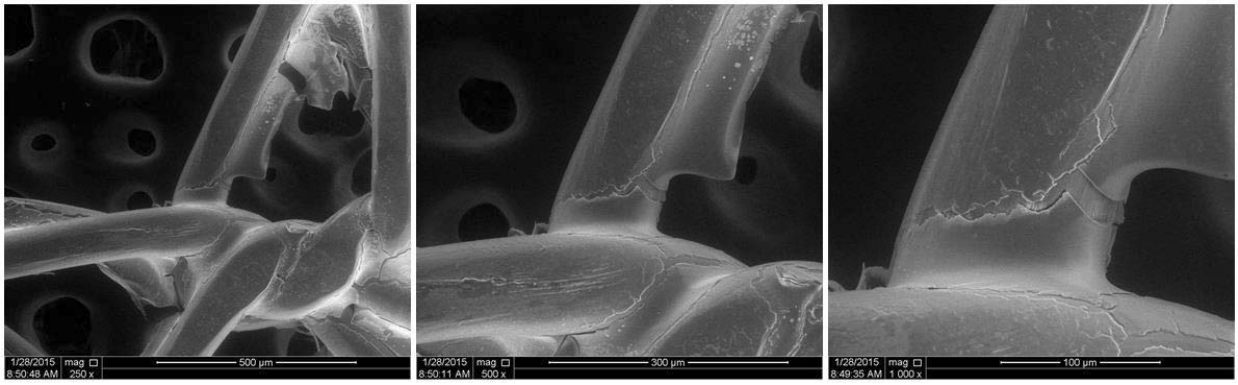

Figure 21 Exemplar mesh after being soaked in human serum for 7 days, mechanically flexed and allowed to dry in air. The deposited film is brittle.

4.2 Mesh explants are not oxidized

Previous Plaintiffs' experts have suggested that mesh explants may be oxidized *in vivo*, and that this is a defect that causes various health risks and adverse outcomes. I disagree with this opinion from the perspective of a polymer scientist and researcher in the field of polymers and biomaterials. I have provided a basis for my opinion here and in the analyses outlined elsewhere in my report.

Polypropylene can degrade by oxidation, and previous Plaintiffs' experts suggest that the conditions necessary for this to occur are present during manufacturing and while the Bard TVM products are implanted. However, direct evaluation of explanted mesh and challenge testing of exemplar materials demonstrate that the necessary conditions are not present, and that mesh explants are not oxidized.

4.2.1 SEM does not show oxidation of the mesh explants

A primary basis for previous Plaintiffs' experts' assertions of oxidation degradation is the cracked morphology of explants viewed by SEM. A careful review of the images, the sample preparation methods, associated data and the peer-reviewed literature, however, all indicate that the surface features are more likely to be artifacts of normal foreign body responses and insufficient cleaning of deposited material prior to imaging. Other observed features are common for extruded and knitted filaments, or are artifacts of handling and implantation.

SEM, particularly as used and described by Plaintiffs, is not a recognized means of characterizing organic material composition, including the chemistry associated with polypropylene oxidation. It is useful for assessing morphology, and in this case the morphology is of a brittle coating. Complementary data, including FTIR, TGA, and other studies indicate there is a coating deposited on the surface, and that it is not oxidized polypropylene. The layer-like aspect of the coating is visible in many SEM images. In light of this, any coating spalling or particulate from the explants cannot be attributed to degraded polypropylene. To the extent the biofilm coating creates adverse health effects,[86] the outcomes are not because of a defective material, or the defective use of Marlex HGX-030-01 polypropylene.

4.2.2 FTIR does not show oxidation of mesh explants

Exponent's FTIR measurements and analysis indicate the presence of foreign material on the surface of explants, and that remnants of this material can remain after cleaning. This material is not oxidized polypropylene. Plaintiffs' own data shows likewise the presence of the deposited biological material, and indicates variability that is likely related to patient-specific factors. For example, FTIR spectra collected by Polymer Solutions from the explants of three previous plaintiffs and FTIR spectra collected by Jordi labs from the explant of other previous plaintiffs contain peaks associated with functional groups not in polypropylene. Because of the limitations of the technique and the nature of the spectra presented, these peaks are not diagnostic for oxidation, and may more reasonably represent the presence of another material, such as an amide-containing material. Furthermore, the collected spectra indicate the samples are not uniform in composition with varying features in the 1500-1700 cm^{-1} range. Noticeable chemical changes can be seen by analysis of the surface after successive cleaning steps, including repeated rinsing in sodium hypochlorite solution (Align Appendix FF).

There are also variations within a given explant, and between samples obtained from different patients. These variations can be reasonably explained by patient- and site-specific deposits. If these peaks were due to the inherent chemical composition of the material, one would expect

[86] Health effects are beyond the scope of this report.

them to be in each spectrum, regardless of sampling location. Similarly, if these peaks are attributed to a changed chemical composition of the device resulting from use in general, one would expect all explanted samples to have the same peaks. Thus, FTIR data does not provide a sufficient basis to conclude the cracking morphology is from oxidized polypropylene.

4.3 Bard TVM products are not defectively designed or manufactured

Plaintiffs' experts generally have suggested that the Bard TVM products were defective in design or manufacture for reasons that include the materials, knit structure (e.g. pore size and mesh weight), product geometry, and intended surgical approach. I disagree. I have provided a basis for my opinion here and in the analyses outlined elsewhere in my report.

The Bard TVM products are a subset of Bard's larger offering of mesh-based product for soft tissue repair, including the repair of POP and SUI. The materials are biocompatible and stable. The knit structures and product geometries were selected based on testing, surgeon input, clinical history, and institutional knowledge. The devices were manufactured in a reasonable, controlled process. And, from an engineering perspective, the intended surgical approach is one of many options to be selected by a surgeon, not the device manufacturer, based on patient factors and surgeon preference.

The adoption of mesh materials in vaginal repair has evolved from its widespread use in the repair of abdominal wall hernias (Lucente, Murphy et al. 2012). Abdominal hernia repairs with synthetic meshes have been proven to be substantially superior to suture-based repairs, leading to significantly lower recurrence rates. It has been stated that although the female pelvis is different in several aspects when compared with the abdominal wall, nonetheless, similar challenges are faced for non-mesh repair of the pelvic floor as for abdominal wall hernias. A large amount of information has been compiled indicating the reported complications of pain, scarification, dyspareunia, infection, etc. are not the result of defective design or manufacture (See Appendices E-H). The mesh was designed and developed with appropriate pore sizes and mechanical compatibility, which provide adequate function of the mesh.

4.4 Responses to Plaintiffs' Experts

To the extent that Plaintiffs' experts have expressed specific opinions,[87] I have addressed them herein and in prior reports, including by virtue of my findings and conclusions contradicting and refuting those experts' opinions, and my same analysis applies.

[87] Plaintiffs' have disclosed the following experts: Dr. John Miklos, Urogynecology (adoption of reports previously served on 10/9/14 in Wave 1 and 2 and 2/17/15 in Miniwave, updated reliance list served on 05/08/2017 on Waves 4 and 5, and reports previously served on 05/12/2017 in Waves 4 and 5); Dr. Alan Garely, Urogynecology (adoption of reports previously served on 10/9/14 in Wave 1 and 2 and 2/17/15 in Miniwave, updated reliance list served on 5/08/2017, and reports previously served on 05/12/2017 in Waves 4 and 5); Dr. Brian Raybon, Urogynecology (adoption of reports previously served on 10/9/14 in Wave 1 and 2 and 2/16/15 in Miniwave and updated reliance list served on 05/08/2018 in Waves 4 and 5); Dr. Lennox Hoyte, Urogynecology (adoption of reports previously served on 10/9/14 in Wave 1 and 2 and 2/16/15 in Miniwave and updated reliance list served on 05/08/2018 in Waves 4 and 5); Dr. Robert Moore, Urogynecology (adoption of reports previously served on 5/12/2017 in Waves 4 and 5); Dr. Stacey Wallach, Urogynecology (adoption of reports previously served on 10/13/14 in Wave 3 and updated reliance list served on 05/08/2017 in Waves 4 and 5); Ahmed El-Ghannam, Ph.D., Biomaterials (adoption of reports previously served on 10/9/14 in Waves 1 and 2 and 2/17/15 in Miniwave); Julia Babensee, Ph.D., Biomedical Engineer (adoption of reports previously served on 10/9/14 in Waves 1 and 2 and 2/17/15 in Miniwave); Jerry G. Blaivas, M.D., Urologist (adoption of report previously served on 10/9/14 in Waves 1 and 2); Keith O. Reeves, M.D., F.A.C.O.G, Gynecologist (adoption of report previously served on 10/9/14 in Waves 1 and 2); Bruce Rosenzweig, M.D., Urogynecologist (adoption of report previously served on 10/9/14 in Waves 1 and 2).

5 Opinions

Based on the information reviewed and my education, training, and experience in the fields of materials science, polymer science, and medical device product development, it is my opinion to a reasonable degree of scientific and engineering certainty that polypropylene, including Phillips Marlex HGX-030-01, is a reasonably selected biomaterial exhibiting appropriate biocompatibility. It is further my opinion to a reasonable degree of scientific and engineering certainty and/or probability that Bard TVM products based on Phillips Marlex HGX-030-01 polypropylene, exhibit the ability to perform as intended for tissue repair, including the repair of pelvic organ prolapse and stress urinary incontinence. It is also my opinion to a reasonable degree of scientific and engineering certainty and/or probability that the Avaulta Solo, Avaulta Plus and Align mesh characteristics, including geometric structure, pore characteristics, the incorporation of collagen and marking fibers, and biomaterial attributes, are reasonable for use in tissue repair, including pelvic organ and stress urinary incontinence repair, and are consistently described according to a reasonable method. There is no evidence of defective material, design, or manufacturing in Avaulta Solo, Avaulta Plus or Align implants, including those implanted in Plaintiffs. Thus, it is my opinion to a reasonable degree of scientific and engineering certainty and/or probability that there is no evidence that the Avaulta or Align implants, or any action or inaction on the part of Bard related to these products, caused the alleged injuries to the Plaintiffs. All of my opinions expressed below are held to a reasonable degree of scientific and engineering certainty and/or probability.

- Polypropylene, including Phillips Marlex HGX-030-01, is a reasonably selected biomaterial exhibiting appropriate biocompatibility.
- Bard transvaginal mesh products based on Phillips Marlex HGX-030-01 polypropylene, including the Bard TVM products implanted in Plaintiffs, exhibit the ability to perform as intended for tissue repair, including the repair of pelvic organ prolapse and stress urinary incontinence.
- The Bard TVM characteristics, including geometric structure, pore characteristics, and biomaterial attributes, are reasonable for use in tissue repair, including stress urinary incontinence repair, and are consistently described according to a reasonable method.
- There is no evidence of defective material, design, or manufacturing for the Bard TVM implants, including the Bard TVM products implanted in Plaintiffs.

- Polypropylene is a well-accepted biomaterial with a long history of clinical use as a permanent implant.

- Raw material manufacturers' designations or labels such as "medical grade" are not a substitute for biocompatibility testing of a polymer, nor do these designations or labels preclude the material from being biocompatible, or preclude additional testing to confirm a specific product made from a raw material is biocompatible.

- The Bard TVM products made of Marlex HGX -030-01 polypropylene and collagen are biocompatible, and have been repeatedly tested to confirm biocompatibility according to objective and scientific methods accepted by the FDA and other regulatory agencies.

- MSDS language does not affect the biocompatibility or function of the polypropylene material. The Bard TVM products are not defective because of their use of Marlex HGX-030-01 polypropylene.

- The polypropylene mesh used in the Bard TVM products, including the device implanted in the Plaintiff, does not oxidatively degrade in the body. Pathology and histology assessment of tissues are not a means of assessing the presence of polypropylene oxidation. The material is stable against anticipated oxidative challenge by heat and peroxides, including from processing and inflammation. The cracked surfaces of explanted Bard TVM mesh are not due to oxidized polypropylene.

- Plaintiffs' adverse outcomes are not the result of oxidized polypropylene because the polypropylene is not oxidized *in vivo*.

- Synthetic meshes, including polypropylene meshes, are expected to cause a mild inflammatory response for tissue in-growth to occur, but remain essentially inert and stable in the body and exhibit excellent biocompatibility as shown through extensive studies. The extent of inflammatory response varies among patients and is related to patient-specific factors including repair site location, previous medical history, tissue quality, and surgeon skill.

- Any tissue repair mesh may exhibit shrinkage or contracture as a result of normal healing action on the implant and identical products can exhibit widely varying levels of tissue contracture because of implantation and patient-specific factors. As a result, a reliable correlation between the degree of shrinkage and mesh material or construction has not and cannot be made.

- The Bard TVM products, including the product implanted in Plaintiffs, were constructed of widely-accepted biomaterials with a successful history of clinical use in many applications, including tissue repair. The materials were reasonably selected and were appropriate.

- The polypropylene mesh used in the Bard TVM products, including the Bard TVM products implanted in Plaintiffs, was reasonable, biocompatible, and acceptable.

- The design and development process associated with the Bard TVM products, including the Bard TVM products implanted in Plaintiffs, was performed in accordance with accepted and expected engineering and scientific practices. The process built on Bard's prior experience, testing, and history with Bard's polypropylene meshes and collagen products. This process included identification of required and desirable attributes based on the reasonably anticipated and foreseeable use of the product, review of available information related to design and performance attributes of similar products, testing according to standard and customized test methods, and iterative evaluation of the product.

- The Bard TVM products consistently met or exceeded specifications for product strength and durability. The Plaintiffs' meshes were manufactured in accordance with the product specifications and did not fail to provide the intended soft tissue support.

- Bard's designs, manufacturing procedures, and product offerings reflect ongoing assessment of technical capabilities, physician behavior, and market preferences. Bard continued to evaluate and improve its manufacturing processes and existing product designs. Bard also sought to incorporate new materials and implement new manufacturing techniques as they became commercially available or viable.

- Bard acted as a reasonably prudent medical device company in the design, manufacture, and testing of the Bard TVM products, including the meshes implanted in Plaintiffs.

- Bard TVM products, including the Bard TVM products implanted in Plaintiffs, are not defective in design. The designs of the Bard TVM products were state of the art at the time of their development and were appropriate and in compliance with normal scientific, engineering, and regulatory expectations.

- The Bard TVM products implanted in Plaintiffs were not defectively manufactured. The Bard TVM products are assembled from acceptable and validated materials in a specified manner and tested according to quality control procedures. The available information indicates that the Bard TVM products implanted in Plaintiffs met all design and manufacturing specifications.

- There is no evidence of oxidative degradation of the polypropylene in the Bard TVM products implanted in Plaintiffs, therefore to the extent that Plaintiffs alleges injuries are caused by oxidatively degraded polypropylene, this cannot be true.

This report summarizes the results of my document review, inspection, and analysis related to the subject matter. My findings are based on my education, training and experience as well as information presently provided and discovery progresses. My findings may be updated if new information becomes available. I reserve the right to respond to opinions provided by Plaintiffs' experts and to information that is provided as discovery proceeds, including but not limited to

case-specific discovery, medical records, expert reports, and witness testimony, and to supplement this report if necessary or appropriate.

Maureen T.F. Reitman, Sc.D., P.E.
June 24, 2019

Appendix D

Plaintiff Specific Information

PLAINTIFF	Explant
Chrastecky, Donna	No
Katsiafas, Gladys	Yes
Smith, Becky	Yes

Smith, Becky

The following table contains a summary of the devices implanted in Becky Smith.

Device 1 Implanted	Align TO hook
Reference Number	BRD400HK
Lot Number	CVRK0017
Expiration Date	November 2009
Final Lot Size	400
Final Inspection Date	12/14/2007

Device 2 Implanted	Avaulta Plus Anterior
Reference Number	CVRI0022
Lot Number	486101
Expiration Date	August 2008
Final Lot Size	666
Final Inspection Date	9/13/2007

Implant Surgeries	January 15, 2008
Revision Procedures/Surgeries	January 20, 2009; November 16, 2018

EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

\- - -

IN RE: C. R. BARD, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	: MDL NO. 2187
THIS DOCUMENT RELATES TO	:
Becky Smith and Donald Mackie, Plaintiffs, v. C. R. BARD, INC. Defendant.	:Case No. 2:15-cv-16402

\- - -

JULY 29, 2019

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Videotape deposition of DANIEL S. ELLIOTT, MD, taken pursuant to notice, was held at the law offices of Reed Smith LLP, 136 Main Street, Suite 250, Princeton Forrestal Village, Princeton, New Jersey 08540, beginning at 1:27 p.m., on the above date, before Amanda Dee Maslynsky-Miller, a Certified Realtime Reporter in and for the State of New Jersey.

\- - -

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ALSO PRESENT:
Dan Lawlor, Videographer

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None

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(It is hereby stipulated and agreed by and among counsel that sealing, filing and certification are waived; and that all objections, except as to the form of the question, will be reserved until the time of trial.)

- - -

VIDEO TECHNICIAN: We are now on the record. My name is Dan Lawlor, I'm a videographer with Golkow Litigation Services. Today's date is July 29th, 2019, and the time is 1:27 p.m.

This video deposition is being held in Princeton, New Jersey, in the Matter of Becky Smith versus C.R. Bard, Inc., Pelvic Mesh. The deponent is Daniel Elliott. Counsel will be noted on the stenographic record.

The court reporter is Amanda Miller and will now swear in the

witness.

- - -

DANIEL S. ELLIOTT, MD, after having been duly sworn, was examined and testified as follows:

- - -

VIDEO TECHNICIAN: Please proceed.

- - -

EXAMINATION

- - -

BY MR. BUHR:

Q. Good afternoon, Doctor. My name is Eric Buhr, I represent the defendant in this case.

Can you please state your full name for the record?

A. Daniel Stephen Elliott.

Q. And you understand you're here today as a retained expert for Becky Smith in her case against C.R. Bard?

A. Correct.

Q. Is there any reason you cannot understand and answer my questions

to the best of your ability today?

A. As long as they're stated clearly, no.

Yes.

Q. Fair enough.

You've been deposed several times in the past; is that right?

A. Correct.

Q. You feel comfortable with the deposition process and the rules we typically like to follow?

A. Yes.

Q. So I won't go over the typical admonitions, then.

But I will say that with the video conference here with the slight delay, make a special effort, and I'll do the same, to let each other finish and not talk over each other for the sake of the court reporter and just understanding each other.

Is that fair?

A. Yes, it is.

Q. Let's start with just

housekeeping and attach as Exhibit A a copy of the deposition notice.

- - -

(Whereupon, Exhibit Elliott-1, Notice of Videotaped Deposition of Dr. Daniel S. Elliott, was marked for identification.)

- - -

BY MR. BUHR:

Q. Doctor, have you seen this deposition notice before today?

A. Yes, I have.

Q. It includes a long list of document requests. And I won't go through each one of them.

I understand from our discussion off the record that you've already produced most or all of the records that would be responsive, except, perhaps, invoices regarding this case.

Is that a correct understanding?

A. That is what I understand as

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well.
Q. So just to be clear, you haven't brought anything with you?
A. No.
You cut out on us a little bit. I think I understood your question, but there was a little bit of a gap there. You may just want to repeat it so I know.
Q. Just to be clear, you didn't bring anything with you today to produce?
A. That is correct, I did not bring anything.
Q. You've been retained on behalf of Wagstaff Cartmell to provide expert testimony in this case; is that right?
A. Correct.
Q. And you previously provided expert reports and provided expert testimony in this MDL against C.R. Bard; is that right?
A. Correct.
Q. And, in fact, you previously

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provided a generic report on the involved products and were deposed on those generic opinions; is that right?
A. Correct. Several years ago, yes.
Q. So we'll try not to tread any old ground on those generic opinions.
So today we're specifically discussing your opinions regarding Becky Smith. Is that consistent with your understanding?
A. Yes, exactly.
Q. Do you recall when you were first retained by the Wagstaff firm to provide expert opinion in Bard cases?
A. I don't recall the exact time. I know I gave a general report and deposition four, five years ago. But I don't have the exact timeframe of that, though.
Q. Do you know how many Bard cases you have provided expert opinion in?
A. Off the top of my head,

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without a -- I would say three or four perhaps.
Q. Do you know the total amount of time that you've spent in this litigation against Bard?
MS. SCARCELLO: Object to the extent it calls for testimony about general opinions.
THE WITNESS: No, I don't. I don't have that number.
BY MR. BUHR:
Q. Do you have any general estimate of the amount of hours you spent on the C.R. Bard cases?
MS. SCARCELLO: Same objection.
THE WITNESS: I don't keep any record.
BY MR. BUHR:
Q. You don't keep invoices that you submitted to the Wagstaff firm?
A. No, I do not.
Q. And am I correct that you charge $700 per hour for case review and

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testimony?
A. Correct.
Q. Am I correct that you've also provided expert testimony in a number of pelvic mesh cases against Ethicon?
A. Correct.
Q. And are you retained through the Wagstaff firm for those cases as well?
A. Yes.
Q. Do you recall approximately how many Ethicon cases you've provided expert testimony in?
A. I don't have an exact number. The majority of the work would be done with Ethicon as opposed to Bard, though.
Q. Have you provided expert testimony in any other pelvic mesh litigation other than Ethicon and C.R. Bard?
A. There was work done early on against -- with the Cook product, which

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is a non-mesh. And then a little bit of work with the AMS products. I don't know how far those extended, but I didn't do any patient case-specific reviews, and I do not believe I turned in any general expert report. But I looked at issues originally.

Q. Do you have any estimate for how much time you spent specifically on the Becky Smith case?

A. I don't have an exact number. That work was done in May of this year and sent to the Wagstaff firm. So they have that, which I've been told will be provided to you.

Generally, they take several hours or more. But I don't have a specific recollection of this one.

Q. So when you say "they have that," are you referring to an invoice for your time?

A. That is correct.

MR. BUHR: And then, counsel, I know we mentioned this

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prior to the deposition, but for the record, you'll agree to produce those to our offices, whatever invoices you have specific to this Becky Smith case?

MS. SCARCELLO: Yes.

BY MR. BUHR:

Q. Have you spent additional time since the submission of those invoices, or invoice, around the May timeframe?

Do you have an estimate for how much additional time, if any, you've spent on this case?

A. It's been several hours spent this month alone. So since May, there's been none until this month, July. And, again, that would be several hours reviewing depositions and expert reports.

Q. So, then, would it be approximately six hours you spent in total on this case, if I'm understanding what you said, in your time spent in May and your time spent in July?

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MS. SCARCELLO: Object to the form of the question.

THE WITNESS: I would just -- I would have to be guessing, because I have not seen that May invoice. I would suspect the May invoice would be around the four- to seven-hour range. Again, that's very much of a guess.

And then in July, it's around the same amount of time.

BY MR. BUHR:

Q. I assume you haven't submitted your -- an invoice for your July time; is that right?

A. That's correct. That will be done at the end of the month. So in a few days.

MR. BUHR: Let's go ahead and attach your case-specific expert report as Exhibit-2, I believe it would be.

- - -

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(Whereupon, Exhibit Elliott-2, Case-Specific Expert Report, was marked for identification.)

- - -

BY MR. BUHR:

Q. So what we've attached as Exhibit-2, does that appear to be your complete expert report in this case?

A. It appears to be signed and dated May 24th, 2019. It includes my report, my -- and my C.V. and my reliance list.

Q. And does this report contain all of the opinions that you intend to offer in this case specific to Becky Smith?

A. Up to this point, yes. If new material becomes available, obviously, that would change. But as of today, July 29th, this is complete.

Q. And can you generally describe for me how you go about forming your opinions?

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A. Forming my opinions on this case or anything I do in my normal daily work would be the same. It would be reviewing the outside medical records, talking with the patient usually, though in this case I can't talk to her, obviously, and based upon my experience, my review of the medical literature, discussions with colleagues, et cetera, come up with an opinion ruling in or ruling out various different pathologies.

Q. And so Exhibit B to your expert report is your reliance list.

And that's everything you relied on in forming your opinions at the time of your expert report, correct?

A. Correct.

Q. And how did you go about compiling these materials?

A. As part of my usual, I ask whatever law firm it happens to be, this time, obviously, it's Wagstaff and Cartmell, give me all medical records that are available, all depositions, all

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expert reports, everything. And then I review whatever they give me.

Q. Did you feel you had adequate materials to form your opinion at that time?

A. Yeah, at that time. Yes. There's been added on since that time, with depositions of the implanting doctor and one of the revision surgeons, and then the -- what would you call it? The defense expert witness. I've reviewed that since then.

Q. What do you mean by --

A. But my opinions did not -- Sorry, go ahead.

Q. I didn't want to cut you off if you were still finishing your answer.

A. I was going to finish by saying the reviewing of those further documents, the deposition and expert report did not change my opinions significantly, it mainly supported them.

Q. Did you request any additional medical records?

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A. Well, I request all medical records that are available. And so I'm at the mercy of the law firm of giving me whatever they can get ahold of.

If I find an operative note or something that I don't have, I ask them for it. But that wasn't in this particular case. So as far as I know, I've been given all of the records.

Q. And you kind of alluded to this a little bit already, but just to be clear, at the time you formed your opinions and signed your report, you didn't have the depositions of any of the treating physicians in this case; is that right?

A. That is correct.

Q. And did you feel that you could form your opinions without the testimony of the implanting and explanting physicians?

A. I can essentially form my opinions based upon the medical records, and then augment that with the

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deposition.

Had the depositions shown a significant opinion difference or changed my opinion one way or the other significantly, then I would have asked for a supplemental report to be filed.

Q. So several times, I believe, you used the term "significantly."

Did reviewing those depositions after your expert report change your opinions in any way?

A. No, they just reinforced them. So it didn't change. Reinforced.

Q. Did you review the entirety of those depositions or just excerpts?

A. No, as per my usual, I asked for the entire deposition, all however-many-hundreds of pages they are, and then I go through them. So I do not get ever a summary.

Q. Do you get a summary, any type of summary, of the medical records, or do you review those in their entirety as well?

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A. I review them in their entirety. I found that chronologies as provided, they weren't provided in this case, but if they are provided, they tended to not be very accurate. So I did it all myself, every single page.
Q. So, then, just to be clear, even though you reviewed additional materials since you signed your expert report, you still feel it's complete and accurate?
A. Yes.
Q. And it contains all of the opinions you intend to offer and your basis for those opinions?
A. As I stated before, unless new information were to be provided that's not available as of July 29th, 2019. But right now it is complete.
Q. I believe you mentioned reviewing an expert report from the defense.
What specifically are you referring to?

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A. There was a Dr. -- I won't pronounce his name correctly, so I have to apologize -- Guidice, Guidice, something like that.
Q. I say Guidice, but I don't know if that's correct either, to be honest.
So you reviewed his report?
A. Correct.
Q. Did you have any significant disagreements with his report?
A. Yeah, that's a -- we'd have to go through point by point of his report. But, yes, I have some major disagreements.
Q. Did you do anything to specifically prepare for the deposition today?
A. Other than just on my own, reviewing my expert report, as I said -- mentioned earlier, reviewing the depositions from the two physicians and then the expert report, Dr. Guidice, and I had a 15-minute meeting with counsel

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this afternoon.
Q. You had a 15-minute meeting with counsel today?
A. Correct.
Q. And was that with the counsel that's here at the deposition today?
A. Correct.
Q. There was also a subsequent deposition of plaintiff Becky Smith that took place maybe a month and-a-half ago.
Did you review that deposition transcript?
A. I have not seen that one.
Q. So the only deposition of the plaintiff that you've reviewed is the deposition that took place in 2017; is that right?
A. Correct.
Q. Is that something you would like to review, her new deposition?
A. Yes.
Q. And you have not personally examined Becky Smith; is that right?

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A. Correct.
Q. I believe in some prior Bard cases you performed examinations, what we sometimes refer to as an IME.
Do you recall that?
A. Yes.
Q. And why did you not do an IME or any type of examination with Becky Smith?
A. I was under the understanding that there was an agreement that if this case, or whatever you call it, were to proceed forward, then I would do one prior to any trial case.
Q. So is that something you think would be helpful in forming your opinions?
A. Yes.
Q. Have you spoken with Becky Smith?
A. No.
Q. Have you spoken with any of her doctors?
A. No.

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Q. Can you describe generally for me your method in drafting this expert report?
A. It would be the same as all reports I do. I review all of the medical records, write down a chronology with key comments made within the records. From there, formulate a differential diagnosis ruling in or ruling out various different pathologies.
And then I write the report up and then come to conclusions, based upon the information I had at that point in time.
Q. So would you personally take notes as you're reviewing the medical records?
A. No. I do it -- as I go, I write it. So there's no separate set of notes.
Q. And does the report contain everything you ruled in and ruled out in your differential diagnosis?
A. Correct. As what is

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indicated on Page 4 of my report going to Page 5, that would be my standard differential diagnosis.
Q. Did you have any assistance preparing your report?
A. None.
Other than the reliance list. Sorry, I should -- I did not type up the reliance list. I typed up the medical billing records, the depositions and then the Wagstaff firm provided the other. So I did not personally type that up.
Q. I'd like to attach, just for the record, your list of previous testimony that was provided to us. This wasn't attached to your expert report, it was provided to us separately.
MR. BUHR: So I just want to make sure it was attached for the record. Let's do it as Exhibit-3.
- - -
(Whereupon, Exhibit Elliott-3, List of Previous

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Witness Testimony, was marked for identification.)
- - -
BY MR. BUHR:
Q. So is this an accurate list of your previous testimony?
A. Well, I don't keep a list of my testimony, so this would have come from the Cartmell firm. So I cannot attest to the accuracy or completeness of it.
It looks fairly complete. But, again, I don't -- in retrospect, can't say if it's complete.
Q. Can you tell by looking at it what time period this covers?
A. It would cover roughly 2011 to the present.
Q. Does it appear to be roughly in chronological order, to the best you can tell?
A. Well, the very first one says Coloplast versus Generical Medical Devices and the very last one is the same

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thing. So, I don't know, it says, In regards to Mentor ObTape, that was -- wait, I'm sorry, that's different.
I would have to say, yes, it does look accurate. I just don't know why that Mentor -- the last one is Mentor ObTape. I don't know how that fits in there. But it looks fairly accurate.
Q. Do you recall roughly when you last testified?
A. Well, "testified," do you mean -- does that mean a deposition?
Q. Yes.
A. Or a trial, in the courtroom?
Q. Either one.
A. Last deposition I gave was last weekend. Last time I was in a courtroom was February of 2018.
Q. Is your deposition last weekend listed on this report?
A. No.
Q. So what case was that in?
A. That was a deposition --

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case-specific depositions on three Bard cases -- excuse me, three Ethicon cases and one Bard case.
Q. What was the product at issue in the Bard case?
A. Avaulta. And the individual also had an AMS sling, but that was not part of the deposition.
Q. And what were the Ethicon products involved in those cases?
A. Two Prolift?s and one TVT-O.
Q. Is the Prolift? a product to treat pelvic organ prolapse?
A. Correct.
Q. And the TVT-O is a pelvic mesh product to treat stress urinary incontinence?
A. Correct.
Q. And you provided expert opinion that those products were defective and caused injury; would that be right?
A. Correct.
Q. And with respect to your

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courtroom testimony in February 2018, do you recall what case that was and what it involved?
A. It was a Prolift? case with Wagstaff Cartmell in Indiana, if that helps.
Q. Are there additional Ethicon products that you provided expert opinion on?
A. TVT as well, and TVT-Secur.
Q. And your opinion is all those products were defective and caused injury?
A. Correct.
MS. GRIFFIN: Eric, just for the record, that came in a little spotty, in case you want to repeat that.
MR. BUHR: Thank you for that.
BY MR. BUHR:
Q. So you provided expert opinion that all the products you just listed from Ethicon were defective and

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caused injury; is that right?
A. Correct.
Q. So turning more specifically to Becky Smith, you referenced your general differential diagnosis list on Pages 4 and 5 of your report, correct?
A. Yes.
Q. And you were able to rule all of those out as potentiality alternative causes?
A. Well, no, I don't rule them all out, because some of those include mesh complications. So some of them are ruled in, some of them are ruled out. The majority are ruled out.
Q. So you ruled out everything other than those related to mesh?
A. Well, we would have to go -- sure, I don't want to make a blanket statement and miss something here, but either mesh or mesh-specific complications, yes, I ruled them out.
Q. So just to be clear as a starting point, that I understand the

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opinions that you intend to offer here, with respect to Becky Smith's specific injuries, am I correct that you're offering an opinion that the Bard mesh implants caused plaintiff, Becky Smith, pelvic pain and dyspareunia and mesh extrusion?
A. As summarized on Page 18 of my report, starting on Page 18, yes, pelvic pain, vaginal pain and dyspareunia resulting from the complications caused by the presence of the mesh in her body.
Q. So just to be clear, you're not offering an opinion that she has any other injuries such as voiding dysfunction or anything like that, right?
A. Well, voiding dysfunction can be caused by the presence of the mesh, the removal of the mesh, or dysfunction caused by. So we would have to be very specific.
From what I understand, as of now she was not complaining of significant voiding dysfunction. But if

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you had something, I'd have to see it in the records. I didn't see that.
Q. Well, I didn't see anything either. I just want to make sure that what you're alleging her injuries are related to the mesh is encompassed by pelvic pain, dyspareunia and extrusion requiring removal of the mesh, correct?
A. Correct. As of right now, yes.
Q. You're aware that plaintiff has complained of fecal incontinence; is that right?
A. Yes.
Q. And you're not offering an opinion that that was caused by the mesh; is that right?
A. As of what I know right now, it is very difficult to draw a logical physiologic relationship between the presence or absence of the mesh or surgery for the mesh causing fecal incontinence.
Q. So you are not offering an

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opinion that her fecal incontinence was caused by the mesh?
A. Well, as I stated, as of what I know right now, I cannot draw a logical connection between the mesh and the surgery to remove the mesh with fecal incontinence.
Q. And you would agree that plaintiff's treating physician, Dr. Denman, also concluded that the -- her fecal incontinence was not related to the mesh; is that right?
A. Yes.
Q. Is it your opinion that both the Avaulta and the Align are responsible for her injuries?
A. They are both contributing.
Q. Can you say what percentage of her injuries are related to the Avaulta versus the Align?
A. It's very difficult to assign a percentage. However, due to the significantly enlarged volume of the Avaulta mesh, the multiple arms and the

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collagen coating, it is going to be more responsible than the TVT-O -- excuse me, the Align.
Q. But you intend to offer an opinion that the Align is responsible for her pelvic pain and dyspareunia?
A. It will be a contributing factor. Since the mesh is identical and it's going in the same obturator foramen, it is not going to be helping any.
What I'm saying is, I cannot assign a percentage. More likely, the Avaulta is going to be the much greater percentage, just, as I mentioned, due to the volume and the presence of the collagen coating.
Q. And you're saying that the mesh of the Align and the Avaulta are identical?
MS. SCARCELLO: Object to the form.
THE WITNESS: No, they are not identical. The meshes are quite similar. But the Align does

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not have a collagen coating like the Avaulta Plus, which Ms. Smith has, or had.
BY MR. BUHR:
Q. Are you offering an opinion that the extrusion was related to the Align product as opposed to the Avaulta?
A. From what I understand at this point, the Avaulta product was the product that had extruded, not the Align.
Q. I understand, from your prior testimony -- well, let me confirm if my understanding is correct.
Have you ever implanted a transvaginal mesh for pelvic organ prolapse?
A. No. I have chosen not to do that.
Q. Have you implanted midurethral slings made out of polypropylene?
A. Yes.
Q. Have you ever implanted the Align?

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A. No.
Q. What midurethral slings have you implanted?
A. I've gone through a series of them and had problems, and that's why there's been a series.
I started with the Mentor ObTape in the early 2000s, probably 2002 or '03, around that time. We obviously had major problems with that. Then I switched to the AMS product called the Monarc, used that for a couple of years. But we had a significant amount of problems of pain for the patient for that, so I stopped that. And then used the Coloplast product, their transobturator sling.
Q. And is that made of polypropylene?
A. Correct.
Q. And it's implanted transobturally -- through the transobturator, sorry, similar to the Align sling; is that right?

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A. Correct. It's a transobturator sling, correct.
Q. And would you agree that all of those products have a risk of pelvic pain and dyspareunia?
A. All the mesh slings, to a varying degree, have a problem with dyspareunia, scarring, mesh contraction, foreign body reaction; so yes.
Q. And that includes the Coloplast sling?
A. Correct.
Q. And you still implant that today?
A. Very rarely. I used to, and then as of 2011 or so, the numbers plummeted to one or two a year from a high of about 100 to 150. And now there's maybe a few a year I do. I can't give you an exact number, roughly 5 out of 100 a year for unique patient situations.
Q. Do you agree that the midurethral slings made of polypropylene

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are within the standard of care?
A. In the properly consented patient and with a surgeon who knows what they're doing and can handle the complications, it is within the standard of care.
Q. Are they generally considered safe and effective in the medical community?
A. The general community? I can't speak for everybody. But there have been position statements making that, that's what they state.
Q. Are you referring to the AUGS position statement?
A. That's one of them.
Q. Are you a member of AUGS?
A. Yes.
Q. Do you agree with that position statement?
A. I agree that it has been the -- that statement is long, with multiple points to it. So I can't give a blanket yes or no to it. We'd have to go

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through each point.
But I agree it has been studied, and I agree that there have been advances with that product. But there have also been significant complications associated with it. And that's where the problem occurs with me.
Q. So at the time of Ms. Smith's implant in 2008, you agree it was within the standard of care for Dr. Kim to implant the Align midurethral sling to treat her stress urinary incontinence; is that right?
A. Correct. I have no fault with Dr. Kim for implanting that at that point in time.
Q. Right. And one of the opinions listed in your report is that the treating doctor, including Dr. Kim, acted within the standard of care.
Is that an opinion that you intend to offer?
A. Yes, I agree with that, in 2008 when it was put in.

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Q. Do you also agree that it was within the standard of care in 2008 to implant mesh for treatment of pelvic organ prolapse?
A. Correct. As of January of 2008, I agree that was within the standard of care.
Q. So you agree it was within the standard of care to implant the Avaulta Plus in 2008?
A. Well, in 2008, we were in our very infancy of knowing what was going on with meshes. I had chosen not to implant meshes, I didn't see a benefit for them, but I didn't feel they would be wrong. We were seeing increases in complications slowly rolling in.
But as of January 2008, when that was implanted, I would find no fault in that, it was within the standard of care. So I agree with what I've stated in my report.
Q. Would it be within the standard of care to implant mesh to treat

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pelvic organ prolapse -- well, strike that.
Would it be within the standard of care in 2008 to implant the Avaulta Plus if the patient did not have pelvic organ prolapse?
A. Well, it is -- the Avaulta or the Avaulta Plus, Avaulta Solo, is defined for prolapse. If a woman has absolutely no prolapse, you would not want to implant it, because it's designed to treat prolapse.
Q. What if the patient had a mild prolapse but was asymptomatic, would it be within the standard of care to implant the Avaulta mesh?
A. That becomes a judgment call. That one has to be a discussion with the patient. If you are going in to operate already for another indication, and they have a low-grade prolapse, it depends what grade you're talking, we have to use specifics.
Technically, for the female

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pelvic mesh and reconstructive surgery exam, if you have a grade 2 and above, it's acceptable to treat. But it has to be a discussion with the patient.
Q. The doctor that performed a hysterectomy at the same time the mesh was implanted was Dr. Crawford; is that right?
A. Correct.
Q. Were you aware that Dr. Crawford found that Becky Smith did not have any significant cystocele?
A. That's what I've heard, yes.
MR. BUHR: And let's just go ahead and attach that record as Exhibit-4, just to make sure we're looking at the specifics.
- - -
(Whereupon, Exhibit Elliott-4, 11/15/07 Dr. Julie Crawford Medical Note, was marked for identification.)
- - -
BY MR. BUHR:

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Q. Do you have that record in front of you, Doctor?
A. Yes, I do. I have, as you said, Exhibit-4. And this is dated November 15th, 2007. It's a note by Dr. Kim -- no, I'm sorry, Dr. Crawford, Julie Crawford.
Q. And if you turn to -- well, before we get there. On Page Bates number 8, they list the past surgical history.
Number 2 is, Prior bilateral tubal ligation.
Can you explain what that is?
A. That's for -- most likely, for sterility. So they ligate the tubes, analogous to a vasectomy in a male. It was done laparoscopically.
Q. Is that a procedure that can lead to any type of pelvic pain or dyspareunia?
A. It would be exceedingly rare. That's a small procedure done

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laparoscopically with small cameras. So I'm sure we can find a case report here or there, but this would be an exceedingly small risk.

Q. Is it possible to develop adhesions following that type of procedure?

A. Adhesions could happen up in the abdomen.

Q. And adhesions are essentially scar tissue, right?

A. They are a type of scar tissue.

Q. And they can lead to pain?

A. There have been reports of that, yes.

Q. Is this something you considered in your differential diagnosis of Becky Smith's pelvic pain and dyspareunia?

A. Correct. And prior to her surgery, her implant surgery on January 15th, 2008, I did not see any record of pelvic pain.

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Q. So you ruled it out because she didn't complain of any pelvic pain at that time?

A. Correct. Following the surgery, adhesions, et cetera, you're going to have -- it's not a delayed development like we see in the meshes; it's immediate. And there's no record of anybody attributing any abdominal pain, pelvic pain, attributing it to any adhesions.

If you have those records, I'd like to see it. I did not see anything in the records.

Q. They also list a 2003 endometrial ablation.

Can you describe for the jury what that is?

A. Well, that falls definitely into the benign GYN land, which I do not do these procedures. Usually, this is done for uterine fibroids; usually. And it's to help reduce the severity or bleeding, abnormal bleeding, caused by

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the fibroids.

Q. Are you familiar with the potential complications from that type of procedure?

A. I do not do that procedure, but I am familiar with the types of pain that they could have. Same thing with fibroids.

And, again, as I mentioned before, I didn't see anything documented in the records attributing any of her conditions, prior to her 2008 surgery, to procedures such as that.

Q. Under medications, she's taking Lexapro.

And I think you note in your record that she had preexisting depression prior to the implant meshes, right?

A. Correct.

Q. Going on to the next page, Dr. Crawford performed an exam, right?

A. Correct. Starting on the Bates number 8 going to, it looks like,

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just 9.

Q. And the vaginal exam notes, No evidence of a significant cystocele or rectocele, appears well supported.

Is that right?

A. That is what she states as of November 15th, 2007.

Q. And that was just a month prior to her implant surgery, right?

A. Well, technically, like two and-a-half months. But it was close. Because her surgery was -- actually, it was, like, two months.

Not to be difficult, just for specifics here. January 15, '08 was her surgery.

Q. You're right.

So about two months prior to her surgery, Dr. Crawford did not find any evidence of a significant cystocele or rectocele?

A. Correct. On her exam on that day, that's what she reported.

Q. And then she sees Dr. Kim a

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few weeks later, on November 30th.
MR. BUHR: And let's go ahead and attach Dr. Kim's records as Exhibit-5.
- - -
(Whereupon, Exhibit Elliott-5, 11/20/17 Dr. Kim Medical Record, was marked for identification.)
- - -
BY MR. BUHR:
Q. Do you have those records in front of you now, Doctor?
A. Yes, I do.
Q. So on Page -- if you go to Page 12 and 13 of the Bates numbers, this is the visit with Dr. Kim on November 30th, 2007.
A. Correct.
Q. And under assessment -- actually, under examination, it says she does have a grade 1 to 2 cystocele and a mild rectocele.
Do you see that?

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A. Yes, I do.
Q. And what symptoms can cystocele and rectocele cause?
A. Fullness, pressure, sensation of something falling out; asymptomatic, retention of urine, retention of stool.
Again, I think I mentioned pelvic pressure. Symptoms such as that, or those.
Q. Prolapse can cause pelvic pain and dyspareunia, too, right?
A. Well, pelvic pain, not necessarily. Pelvic pain would be different.
Pelvic pressure can -- it can interfere with sexual activity, depending upon the severity of the prolapse. They should be very specific.
Pelvic pain is not something we normally attribute, unless it's a major, major prolapse where the vagina has everted itself and it's irritating on the clothing and things.

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Q. And Dr. Kim did not repair the mild rectocele, right?
A. Correct.
Q. So would you agree that the grade 1 to 2 cystocele is a mild cystocele?
A. Grade 1 is mild. Grade 2 is not. It's in the realm of more significant. And prolapses vary from day-to-day depending how the woman is, the time of day, how much standing they have been doing. So it's not uncommon to have a variable exam.
Q. Going back to Dr. Crawford's records --
MR. BUHR: Actually, do we have her January 10th, 2008 record?
MS. GRIFFIN: We do. And that can be marked as Exhibit Number 6.
- - -
(Whereupon, Exhibit Elliott-6, 1/10/08 Dr. Julie

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Crawford Medical Record, was marked for identification.)
- - -
BY MR. BUHR:
Q. Do you have that record, Doctor?
A. Yes, I do.
Q. On Bates number ending in 27, under the physical examination, about three or four sentences above the end of that paragraph, it says, On my exam, there is no evidence of significant cystocele or rectocele and she appears apically supported. However, on exam by Dr. Kim, she has a mild rectocele and cystocele.
Do you see that language?
A. Yes, I do.
Q. So do you have any criticism of implanting the Avaulta product in a patient with only mild cystocele and is asymptomatic?
A. I have criticism of implanting the Avaulta product. However,

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on Dr. Kim's examination, grade 1 is low, grade 2 is acceptable. And so that becomes a judgment call by the doctor who is there. And, as I mentioned, prolapses vary from day-to-day.

If I were operating with a doctor who I felt was doing something wrong, I wouldn't operate with him. I wouldn't do a combined case. Dr. Crawford just mentions it, so I don't have a criticism, really. If it were only a grade 1, that would be different. But it reports grade 2.

Q. And you agree she was asymptomatic at this time with respect to her cystocele?

A. I didn't see anything in the records indicating significant prolapse symptoms.

But they were going to be doing an anti-incontinence procedure, so it's quite common to do a combined repair when you're doing that, because otherwise it will affect your incontinence

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procedure.

Q. So you stand by your opinion that Dr. Kim acted within the standard of care?

A. I would -- if I were in the same situation, I would not have done an Avaulta product. I would have done the anterior repair at the time of the sling surgery.

Because when you're repairing incontinence, if you don't repair concurrent prolapse, if you find a grade 2, that can affect your repair. So it's not uncommon to do a prophylactic either incontinence procedure or a prolapse repair.

If Dr. Kim had repaired the posterior, I would have a major problem with that. But anterior compartment, it's a judgment call, so I don't criticize it.

Q. Would you agree that there are risks associated with any implanted product?

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A. Well, it depends what type of implanted product we're talking about, and the severity and the progressive nature of them can vary tremendously. But procedures do have risks.

Q. And we talked about some of the other transvaginal mesh products where you provided specific opinions in other litigation.

Would you agree that all transvaginal mesh products for pelvic organ prolapse and stress urinary incontinence have risks?

A. So I just want to make sure I heard your question correctly.

You stated all pelvic organ meshes for prolapse and slings have risks; is that -- am I correct?

Q. Yes, essentially.

A. Okay.

Yes. To varying degrees, yes, they do.

Q. And they all have the risk of extrusion, pelvic pain and

Page 57

dyspareunia?

A. Yes, to varying degrees; as long as we're still talking about pelvic organ meshes and slings, they all do to varying degrees.

Q. Would you agree that these are common and well-known risks?

A. I agree that they are common. I disagree that they are well known, the true incidence is not usually disclosed. It is becoming much more well known since 2011.

Q. And if I understand your report correctly, you intend to offer an opinion that Dr. Kim was not advised of all the potential risks?

A. What I'm saying is as far as the level of disclosure of the known risks with the Avaulta, the Avaulta Plus, and the Align, that was not fully disclosed, so Dr. Kim would not be able to know those full risks, as I do, having read internal documents, e-mails, et cetera, as outlined in my general report.

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Q. Would you agree that Dr. Kim is the better authority on what she knows and what she doesn't know?
A. No. She knows only what she knows, but she doesn't know what I know.
And important -- an important part of that is, I've had a chance to review internal documents, which I'm under a confidentiality agreement, so I can't discuss that, even with my own colleagues, I can't discuss -- or, I don't know if I can discuss it so I don't. So they don't know what was known at the launch of the product and everything.
Dr. Kim knows everything she knows. But, again, she doesn't know what else there is out there to know. The old phrase "you don't know what you don't know" type of thing. That's very confusing, however, it's very accurate.
Q. She may not know everything that you know, and it's equally true that you may not know everything that she

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knows; is that fair?
A. Yes, to a certain extent. I have an advantage of being at a large teaching institution, attend meetings nationally, internationally, speak on this subject, and have read internal documents from, essentially, all of the producers of meshes.
There is the chance she knows something I don't. This is not a criticism of her by any means, but that's unlikely. So I am playing the overwhelming odds I have -- I've had an opportunity to know and learn more than she has.
But, again, that's not a criticism of her, by any means.
Q. I guess the point I'm trying to get at is, if she says that she's aware of the risk of extrusion, you're not in a position to disagree with her; is that fair?
A. We would have to ask her what percentage. It's a vague, are you

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aware of the risk of a fuel pump going out in a Mustang? Well, I don't know, I think I do.
But specifics. Is she going to be able to say, yeah, it's 12 to 22 percent, based upon e-mails that we've seen from internal documents; or is she going to go on the literature or is she going to go off the IFU, which doesn't tell us any risks?
So we would have to ask her specifically, what are -- what percentage of individuals have mesh contraction, extrusion, et cetera, progressive nature. And if she gave me a percentage, then I would be more likely to agree or disagree with your comment.
Q. So is it your position that she can't understand the risks of the product sufficiently if she doesn't know the exact percentage of every potential risk?
MS. SCARCELLO: Objection to form.

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THE WITNESS: Yeah. With patients, I feel we have an obligation to tell them, you have a 1 in 5 percent risk of X, Y or Z complication.
The word significant, minor, rare, don't mean anything to an individual patient. That's been studied; that's, you know, in some of my reports. I think we have to give numbers to those.
So Dr. Kim has a good education, I don't doubt anything like that. But, again, I just don't think she -- she never had a chance to know all that could go wrong with the product.
BY MR. BUHR:
Q. Did you read her deposition testimony when she talked about her knowledge of the risks?
A. Yes.
Q. Do you agree that she testified she was aware of the risk of

Page 62

extrusion?
A. Yes. And I also know that a doctor is not going to tell you that they did not know, because they're opening themselves up. So I agree that's what she stated.
Q. And she also testified that she was aware of the risk of chronic pelvic pain at the time she implanted these products?
A. Correct, that's what she stated.
Q. And she also testified that she was aware of the risk of chronic dyspareunia associated with these products at the time she implanted them in Ms. Smith?
A. That is -- that is what she states.
Q. If Plaintiff would have received a different transvaginal mesh product, would you agree that she still may have had pelvic pain and dyspareunia?
MS. SCARCELLO: Object to

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form.
THE WITNESS: Well, as I've stated before, the various different mesh products all have different sets of complications, depending upon the composition of the mesh, plus or minus having a collagen -- or a, excuse me, a protein coat to them.
But there is significant level of risk with all of them.
BY MR. BUHR:
Q. So you're not saying that if she used a different product it would have eliminated her risk of pelvic pain or dyspareunia; is that fair?
A. Well, Avaulta is unique -- the Avaulta Plus, excuse me. It is unique with that extra layer on it, which has never been shown to have any potential benefit.
So I can't state that she would have had more or less with the other ones, but the other ones don't have

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that coating to it. So you're not going to be lowering the risk any.
Q. Would you agree that a hysterectomy can cause pelvic pain and dyspareunia?
A. In specific locations, in varying severity and progressive nature of it, it can be associated with pelvic discomfort.
Q. Is that something you considered in your differential diagnosis?
A. Yes.
Q. Is that listed anywhere in your report as something you considered in your differential diagnosis?
A. When I review the location and the descriptions of the other doctors, and their palpation of mesh contraction, I am going to automatically rule out hysterectomy-related pain, because that's not going to cause -- or be associated with mesh contraction and palpation tenderness.

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Q. Is it possible that some of her pain is related to the hysterectomy?
A. On the anterior vault and obturator space, no.
It's going to be in varying degrees. So I can't completely, 100 percent, rule out everything. I have to look at the data and my experience, and that's what points to the mesh.
Because the vaginal vault discomfort after a hysterectomy is different, it's treated differently. We have different successes with it than with the meshes. So that's why I have to -- we have to look at the totality of the patient for that answer.
Q. And would you agree that nowhere in your report do you discuss the hysterectomy as a possible alternative cause or how you ruled it out?
A. I didn't feel I needed to, because I talk about the specific mesh contraction, mesh exposure, tenderness on palpation on the anterior vault. That's

Page 66

away from where the hysterectomy was performed.

So my experience, on a daily basis dealing with women who have had hysterectomies, we don't see discomfort in that region. So we're talking about a different region.

Similar, I don't talk about ovarian pain or ovarian cysts, because it's a different location, different intensity.

So I don't specifically state it that way, and I didn't feel I needed to.

Q. Did you review the consent form from Dr. Kim?

A. Yes. And I have -- I believe, the consent form, I make a reference to on November 30th, 2007. It's on Page 11 of my report, where it states, at the very last sentence -- it's the middle paragraph, very last sentence, and it says, A full PARQ conference was held regarding the procedure.

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Q. Did you review the actual consent form for the operation?

A. I don't recall -- I mean, I reviewed whatever was there. I'd have to go look. I don't recall the specific page. I'd have to look at it.

MR. BUHR: Let's attach as the next exhibit, I think is Exhibit-7, the consent form.

- - -

(Whereupon, Exhibit Elliott-7, 1/11/08 Consent Form, was marked for identification.)

- - -

BY MR. BUHR:

Q. Do you have that in front of you now, Doctor?

A. Yes, I do, dated January 11th, 2008.

Q. And under the risks section, do you agree it discusses the risks of further procedures, pain, scarring, wound problems, sexual dysfunction, dyspareunia, malfunction of implanted

Page 68

devices?

Those are all risks included on this form, correct?

A. Yes. This is a generic form. They also have cure cancer, persistent stones. This is just a generic consent, not a specific one.

But they mentioned the things you mentioned. They also talk about impotence, women don't have impotence. And ejaculatory dysfunction. Well, women don't have that either.

So this is just a cookie-cutter form.

Q. But it does include the risks of dyspareunia and pelvic pain that we discussed?

A. With no description of the severity, the progressive nature of it, the inability to cure it. Those things are mentioned in a generic form -- generic fashion, excuse me.

Q. Are you also intending to offer an opinion on the adequacy of the

Page 69

IFU warnings?

A. For a general report, not for a case-specific. I don't know how that legal stuff goes. It depends what I'm asked.

The IFU, in my opinion, is incomplete, as we discussed in my general deposition several years ago.

Q. And I don't want to re-tread all that testimony.

But I do want to confirm that specifically related to the alleged injuries by Ms. Smith that it specifically warns of dyspareunia and scarification and contraction and extrusion, correct?

A. Correct. That is stated in there in those words that you use, correct.

Q. And did you see Dr. Kim's testimony that she doesn't rely on instructions for use?

A. Correct.

Q. So you're not going to offer

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an opinion in this case, then, that a different warning on the IFU would have made any difference to Dr. Kim; is that fair?

A. Well, what I state is regardless of what Dr. Kim relied upon, the IFU has to be complete with the severity, the frequency, the inability to cure the problems, et cetera, as known by the company.

Q. Right. But in terms of Becky Smith's specific case, you're not offering an opinion that Dr. Kim would have done anything different if a different warning had been provided?

You have to rely on Dr. Kim for that, right?

A. Well, yeah, you're -- ultimately you're right. I can't state what Dr. Kim would have known.

However, had the IFU been fully complete in the severity, the frequency, the inability to fix the problem, Dr. Kim may have heard about

Page 71

that. So I can't speak -- so that would be best addressed to Dr. Kim once she knows all the risks of the procedure.

Q. And did you see her testimony that she had good clinical outcomes implanting both the Align and the Avaulta Plus?

A. I saw that that's what she reported.

Q. And you've never implanted either of these products, correct?

A. I have chosen not to.

Q. Would you agree that Ms. Smith initially healed well following the implant surgery?

A. Correct, as that's what is the usual.

Q. She did not have any extrusion until approximately one year after the implant; is that right?

A. I see, in my records, February 13th, 2008. So you are correct, it's a year and one month later was, I believe, the -- no, excuse me, that's

Page 72

incorrect.

It's April of 2008 that I believe the records state the first mesh exposure. So a year and, what, three months, something like that.

Q. Well, that's one of the things I wanted to talk to you about.

Because I think -- so April 9, 2008 is only a few months after the implant surgery, right?

A. You are correct.

Q. And so I think the date on that is wrong, and we'll pull that out in a second.

A. Okay.

Q. So in her follow-up, her first post-op visits with Dr. Kim, everything seemed to be healing properly, right?

A. That is correct.

Q. There was no sign of any mesh extrusion on January 23rd, 2008 or February 13th, 2008, right?

A. That is correct.

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Q. And she was noted to be doing extremely well by Dr. Kim, right?

A. That is correct.

Q. And at this point, the Align had corrected her stress urinary incontinence?

A. In the records, I believe it states something that she's doing very well without any problems. So the answer to that would be yes.

Q. And the Avaulta had corrected her cystocele?

A. Correct. Completely gone is what Dr. Kim notes on February 13th of 2008.

Q. On what date? I'm sorry.

A. February 13th, 2008, cystocele, quote/unquote, what I have down here is, completely gone. That's on Page 13 of my report.

Q. Right.

And on that date, and I think it's part of, if you wanted to turn to the records, part of Exhibit-5, and

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Dr. Kim notes that the anterior vaginal wall has healed very nicely; is that right?

A. I don't have those records. But that's, from my recollection, correct.

Q. Then turning to this April 9th, 2008 note that you have of possible mesh extrusion. And that would be on Exhibit-5, ending in Bates number 11.

MS. SCARCELLO: Exhibit-5.

THE WITNESS: I'm sorry, Exhibit-5. I thought you were going to hand me something, turns out I already have it.

You said Exhibit-5?

MR. BUHR: Yes.

THE WITNESS: Okay, I'm sorry. And then Bates number?

MR. BUHR: 11.

THE WITNESS: Okay, I'm there.

BY MR. BUHR:

Q. So is this the record you're

Page 75

referring to in your report for April 9th, 2008?

A. Correct.

Q. Is it possible that that handwritten date is actually January 19th, 2008 -- or 2009, rather, and that it was a mistake that's often made in January by writing the prior year, 2008?

A. So you're saying --

Q. 1/19 instead of 4/9?

A. I'm not a, what do you call it, writer expert. I'm just looking at it. I see a 4 and then a 1 with a little slash up, 9, and the slash and up again, 08.

To me it looks like 4/1 -- I mean, we can't be definitive. But, I mean, it looks like my date of April 9th, and you're telling -- you're suggesting what again? 1 --

Q. 1/19 and that they mistakenly wrote 2008 instead of 2009?

A. Well, I -- I don't want to be difficult. To me, it looks like a

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4/1/9 -- I mean, I don't know. If we did 1 --

Q. And I think we do have another copy of this that was in the hospital records.

MR. BUHR: Can we attach it as the next exhibit? Is that Exhibit-8, then?

MS. GRIFFIN: Correct.

- - -

(Whereupon, Exhibit Elliott-8, Hospital Record, was marked for identification.)

- - -

THE WITNESS: If you look down in the history of present illness, 49-year-old female underwent cystocele/Avaulta repair, 1/15/08. Now with mesh extrusion.

So, I mean, it -- I'm going to hold with 4/9/08, unless you have something to be definitive. I'm not going to be --

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BY MR. BUHR:

Q. And the plan there is excision of the mesh, right?

A. Correct.

Q. And you're not aware of any excision of the mesh at that time, in April of 2008?

A. I'm not aware of any, no.

Q. And this is written by Dr. Kim's physician assistant; is that right?

A. I don't know whose assistant it is, but it's a physician assistant.

MR. BUHR: Did we mark Exhibit-8?

MS. GRIFFIN: We did, yes.

BY MR. BUHR:

Q. And you see, Doctor, at the top there, how it lists typewritten, 1/19/2009?

A. Sure.

Q. So just keep that in mind and let me know in a minute if the timing of January 19th, 2009 makes more sense with the subsequent reports by Ms. -- by

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Dr. Kim.
A. Well --
Q. And so, specifically, on -- go ahead.
A. I'm sorry, I did interrupt you. That was my fault. My bad.
Q. So specifically on January 16th, 2009 she returned to see Dr. Kim, right?
A. Yes.
Q. And even according to your report, it says, With a new complaint of vaginal mesh exposure beginning roughly one month prior.
A. Yeah, that's what -- yeah, I must have gotten that from the records.
Q. Right. So this is what she's reporting to Dr. Kim on January 16th, 2009. And you even quote, in your report, About a month ago, her husband noticed some evidence of mesh during sexual intercourse, and this is becoming progressively worse.
Is that right?

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A. Yeah. That's what the report says, yes.
Q. And if you actually look at that report, which is at -- again, it's on Exhibit-5, Bates number ending in 07.
Do you have Bates number 7 in front of you?
A. Yes, I do.
Q. So there in that first paragraph is the language that's quoted in your report that I just read.
And the subsequent sentence says, The patient states that up until a month ago, she did not feel anything at all.
Do you see that?
A. Yes.
Q. So would you agree that that conflicts with the suggestion that the prior report, from Dr. Wyndham, was on January -- sorry. Let me start over.
Would you agree that that conflicts with the suggestion that the report from Dr. Wyndham was April 9th,

Page 80

2008, where she had a plan of mesh excision?
MS. SCARCELLO: Objection to form.
THE WITNESS: Yeah, there's a conflict there.
First of all, this is not to be picky, it's a physician assistant, so it's not a physician.
But, yeah, there is -- there is a discrepancy as far as the dates go. I won't argue with that.
BY MR. BUHR:
Q. So at least according to Dr. Kim's report, she did not feel anything until about a month prior to this January 16th, 2009 report, correct?
A. Correct, that's what Dr. Kim reports.
Q. And then Dr. Kim recommended mesh excision, which took place a few days later on January 20th, 2009?

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A. Correct.
Q. And had she stopped using her Estrace cream at this point?
A. I believe I saw a mention of that.
Q. Can that increase your risk for mesh extrusion?
A. Well, I'm not aware of anywhere it states that with the Avaulta product you have to be on it permanently.
Estrogen can potentially help reduce that risk. But, again, I'm not -- I've never seen where you're supposed to be on it.
Q. No. But Dr. Kim had prescribed estrogen cream following the implant, correct?
A. Correct. And it's not uncommon for women not to like it for some reason, concerns about breast cancer, blood clots and those types of things, to stop taking -- or it's just plain messy. But he did prescribe it afterwards.

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Q. And having a hysterectomy at the same time, would she have had postmenopausal changes after the surgery?
A. No.
Q. Was she found to have vaginal atrophy and thinning tissue?
A. Yes. But she still has her ovaries in place. They were not removed, by her request. So we don't know the volume of estrogen being produced. A 49-year-old female, you don't know.
Q. But Dr. Kim recommended restarting the Estrace cream on January 16th, 2009, based on her complaints; is that right?
A. Yeah. As I have in my -- on Page 13, third paragraph, Dr. Kim recommended restarting Estrace cream. But because of the extent of the erosion, I think this needs to be treated surgically, end quote.
Q. Are there factors that can increase a woman's risk for having mesh extrusion?

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A. I've never read in the IFU factors, which if they are known, they should be in there.
I have seen internal documents that if you have a hysterectomy at the same time, you're increasing your risk for exposure. But, again, that's not in the IFU.
Advanced age probably would increase it. But, again, that's not in the IFU. And presence of an infection would do it.
So there are going to be factors there. But I'm not aware of the company disclosing that they knew of factors. If they did, they should report it.
Q. Well, there's also certain factors that are generally known in the medical community.
For example, would you agree that smoking can increase the risk of extrusion?
A. Excellent point. No. If

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smoking were a risk factor, then that has to be in the IFU, and it's nowhere. At least I haven't seen it. We can pull it out and show it, and I'll change my opinion. But I'm not aware of that.
In fact, some will say the mesh kits are better because a smoker has a chronic cough, so it needs to be a stronger repair. So I'd have to -- I'd have to disagree with you.
Q. I guess my question is more that smoking can have an effect on a patient's tissue quality, right?
A. Yes.
Q. And if a patient has poor tissue quality, that can increase their likelihood for something like extrusion; is that right?
A. I suppose, in theory, that is possible.
As far as I know, Ms. Smith is a nonsmoker, so it's a moot point here. But, again, if meshes have an increased risk of complication like

Page 85

exposure with smoking, then that's got to be on the IFU.
Q. Turning more specifically to Ms. Smith, if she has thinning of the vaginal tissue and vaginal atrophy, can that increase her risk for extrusion?
A. Well, we're talking theoretically here. But the presence of the mesh inside of her body will cause thinning of the vaginal tissue and atrophy appearance, because it is slowly causing a necrosis. So you can't say which comes first.
She's, at this point in time, a 49-year-old female. Theoretically, she should be producing estrogen still. Her ovaries are still in place. So I can't completely agree with you on what's coming first.
Prior to her surgery, there was -- one year prior, there was no indication of vaginal atrophy. Then she has surgery, a mesh is put in with foreign body reaction, inflammation,

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she's getting exposure, which means thinning out. So I would say a logical conclusion, that's due to the presence of the mesh, not due to her.

Q. I think my question was, if a patient has vaginal atrophy, can that increase their risk for extrusion?

A. I know -- I hear what you're saying.

And not to be difficult, we're talking about a theoretical patient, how severe that is, and we're not talking about Ms. Smith.

So we would have to have a specific individual we're talking about how bad this atrophy is. And, again, let's say you are correct, then that's not on the IFU and it's not warned at all. So if that is a known risk, that will be very important to know.

Q. And so are you agreeing with me that it's a factor to consider?

A. Vaginal atrophy would be, definitely, something that you would want

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to consider if it's severe prior to putting in a mesh.

You don't have to worry about that with nonmesh repairs. But in a mesh repair, you would. And it would be a woman's right to know that her body could be permanently harmed if this product is put in. So, for me, it becomes under a woman's rights issue.

Q. Did you consider vaginal atrophy in your differential diagnosis?

A. Yes, I did. By the reasons I have already explained in the last couple of questions ago; 49 year old, she was 48, I believe, at the time of her surgery, she was premenopausal, her ovaries are still in, there's no vaginal atrophy prior to her surgery.

One year later, with her ovaries still in place, we have mesh exposure, thinning and atrophy. And in my opinion, based upon my experience, vaginal atrophy due to menopause takes years and years to develop, it's not

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going to happen in over one year's time. So, then, the culprit becomes the presence of the Avaulta and the inflammatory process it causes.

Q. In the list of examples of your differential diagnosis on Page 4 and 5, you do not list vaginal atrophy or postmenopausal changes in that list; is that right?

A. It is not listed there, no.

Q. In the excision procedure performed by Dr. Kim, she was able to remove the exposed mesh quite easily, right?

A. Yes, she uses those words, "quite easily."

Q. And I believe you said earlier that this extrusion relates to the Avaulta and not the Align; is that right?

A. I'd have to go back and look at the specific operative note. But, as I recall, this is specifically due to the Avaulta, where it is located. It was

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well away from the Align.

Q. And she healed well following this procedure; is that right?

A. Correct.

Q. The anterior vaginal wall completely healed?

A. Yes. As of the note, April 16th, 2009, I believe she uses that word, The anterior vaginal wall has healed up completely. I do not feel any mesh exposure -- extrusion. End quote.

Q. And Dr. Kim prescribed Vagifem tablets on that date?

A. I did not make a record of that. I would have to see the record.

Q. I think it's the first page on Exhibit-5.

A. He gave -- she gave Ms. Smith samples of Vagifem. So she didn't give a prescription, she gave some samples.

Q. And what is Vagifem, for the record?

A. Vagifems are actually

Page 90

estrogen tablets that go into the vagina. They are usually, for most patients, easier to use. They are cleaner. The Premarin cream tends to be quite messy, has an applicator that women don't like.

So Vagifem is just an easier way to insert the estrogen. The problem with it is, it doesn't necessarily stay where you want it to go. But just think of it as a different form of estrogen.

Q. And do you have an understanding as to why Dr. Kim was prescribing estrogen at this time?

MS. SCARCELLO: Object to form.

You can answer.

THE WITNESS: Trying to heal up the vaginal wall or continue to heal it up.

BY MR. BUHR:

Q. Is that something that is needed in order to heal the vaginal wall?

A. Not necessarily, but she was having trouble with the Estrace cream, it

Page 91

was causing irritation. So that could be part of the reason why she stopped it before.

Q. And Dr. Kim obviously felt like it was important for her to have some estrogen cream or estrogen tablets?

A. That would be the standard party line of what you do after a mesh exposure, is to give vaginal estrogen.

But, again, some women can't tolerate it, for multiple different reasons. And if she had trouble with the Estrace cream, which is just a form of Premarin cream, she could also have trouble with the Vagifem, because, it's, again, the same thing, it's just estrogen.

Q. And would you agree at this point in the records there's no documented complaint of pelvic pain or dyspareunia?

A. For her, Ms. Smith, there was no documented pelvic pain or dyspareunia. Her partner had noticed

Page 92

discomfort prior.

Q. And would you agree that the -- she did not complain to a doctor about any problems after this until 2017?

A. I did not have anything in the records from 2009 until March 21, 2017. So I agree with you.

Q. And, in fact, during that period of time, she saw Ms. Hoth for her annual exams and reported no complaints of dyspareunia; is that right?

A. That is correct.

Q. You reference an August 8th, 2013 record from Ms. Hoth where she had bothersome arm pain but no other complaints on that day.

A. That is correct.

Q. Did you see that Ms. Smith actually asked Ms. Hoth on that day about advertisements for vaginal mesh litigation?

A. I remember seeing a reference about that somewhere. I don't -- I'd have to see the specific

Page 93

note.

MR. BUHR: Let's attach as, I believe it's Exhibit-9 we're on now, the record from Ms. Hoth on February 16th -- actually, no. Let's attach the record from August 8th, 2013.

- - -

(Whereupon, Exhibit Elliott-9, 8/8/13 Hoth Note, was marked for identification.)

- - -

THE WITNESS: I have it.

BY MR. BUHR:

Q. And if you'd go to the Bates number that ends in 08.

A. Okay. I'm there.

Q. The top of the next page.

But has no other complaints today. Although has a mesh and is concerned about this, given the current TV ads for, Do you have a mesh, you could be due compensation. Has had sling and had mesh put in when she had the

Page 94

hysterectomy. And then they had to trim it up.

Do you see that?

A. Yes, I do.

Q. So she was specifically asking her doctor about concerns about the mesh, but at this point she was not complaining of any symptoms of pelvic pain or dyspareunia or extrusion or anything like that, right?

A. You are correct.

Q. Just to be clear, your report includes a reference to a February 16th, 2012 report?

A. Yes.

Q. Where you have a reference to pelvic pain with exercise.

A. Correct.

Q. You're not offering an opinion that that pain is anywhere related to the mesh at this point; is that right?

A. I'm just stating what the records stated. The record,

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unfortunately, and what I deal with all the time, is incomplete. It just makes a reference to it.

So I put it down as documentation. But I'm not making a conclusion at that point in time.

Q. So at what point in time are you making a conclusion that she's having pain related to the mesh? Is that in March 2017?

A. Well, I have to go off of the records. All I saw in there, and we can maybe go to that February 16th, 2012 note, if it's there, and that was just in there. That's all it stated.

If it stated more, like it's lifting or a pelvic exam confirms it -- I'm just stating that it is there for completeness sake. But I'm not stating that is due to mesh. All I've got is a statement there. That's all I've got.

So, like, for a differential diagnosis, I don't have enough information to make a conclusion. I'm

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just documenting that that's what's in the records.

Q. Okay. Fair enough.

MR. BUHR: And let's for completeness just go ahead and attach that record as Exhibit-10.

- - -

(Whereupon, Exhibit Elliott-10, 2/16/12 Hoth Office Visit, was marked for identification.)

- - -

BY MR. BUHR:

Q. Do you have that in front of you now, Doctor?

A. Yes. The first page is 2017, so it must be before that.

Q. I think that's the printing date.

If you look on the left side, it should be 2/16/2012 office visit with Ms. Hoth.

A. I have February 16th of '12. Is that --

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Q. Yes.

A. Yes, I have it then.

Q. So towards the bottom of that page, it says, Is pain an issue needing to be addressed today? And it says, No.

Right?

A. Yeah, that's what it states.

Q. And then on Bates number ending in 225, about halfway down the page, it has a list for dyspareunia and then it says no.

Do you see that?

A. Correct, that's what it states.

Q. And then a little bit further down is what I believe you were referring to in your record, under musculoskeletal, where she says, Pelvis with exercise hurts and put back out this Christmas.

Is that what you were referring to in your report?

A. Correct.

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Q. And then if you go onto the next page -- well, she does -- she does an exam?
A. Correct.
- - -
(Whereupon, a discussion off the record occurred.)
- - -
BY MR. BUHR:
Q. And her assessment for the GYN assessment is normal exam, correct?
A. Correct. Note, With fullness, no masses or tenderness. A negative exam.
Q. So then at this point, it's pretty clear she is not complaining of any pain or dyspareunia related to the mesh, correct?
A. Well, as before, she has pelvic -- quote/unquote, Pelvis with exercise hurts and puts -- and put back out this Christmas.
So, again, I am not stating it's due to the mesh. I'm not

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eliminating mesh as an option. I'm not including it. It's just a statement that's there.
But in the physical exam, there was no pain on exam.
Q. So, then, in March of 2017, as we've discussed, is her first real complaint of pelvic pain and dyspareunia related to the mesh.
And she saw a doctor -- or, sorry, a nurse practitioner, Shawn Cool; is that right?
A. Correct.
Q. And this doctor also -- or this nurse practitioner also advised on starting vaginal estrogen cream; is that right?
A. Correct.
Q. And why would she prescribe that at the time?
A. Well, I can't speak for this individual, a nurse practitioner. It's pretty much the standard thing, knee-jerk response, to give estrogen.

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It's not going to change pain. It's for a vaginal extrusion. So I can't vouch for the correctness of that decision.
Q. And you state in your report, Said will trial for two months and see if it provides relief.
A. Correct. And vaginal estrogen in two months is not going to do any good, you need much longer than that.
So that's, reading between the lines, somebody who doesn't deal with meshes. It's not a criticism.
Q. She had no -- sorry?
A. I interrupted.
Q. She had no evidence of mesh extrusion at this time; is that right?
A. All I have down is, on Page 14, during the vaginal exam, Ms. Cool noted that the, quote, bladder sling palpable anteriorly during bimanual exam, end quote.
So there's -- I don't know what that means. Is that exposure or

Page 101

what? We can't put a lot into that, because this is a nurse practitioner not experienced in this.
So I can't say, is that exposure? Is that just that you could feel the scarring and the contraction? I put that in there for thoroughness sake.
She needs -- the patient, Ms. Smith, needs somebody more advanced to be able to give us specifics if we want accuracy.
Q. Do you know if she continued using the estrogen cream?
A. I don't recall. I remember -- I know she's used it on and off. But, again, she had vaginal irritation with it, so I don't -- I can't say how well she used it.
Q. In terms of your differential with respect to dyspareunia and the pelvic pain, did you consider the vaginal atrophy that she was having at this point?
A. Yeah. Vaginal atrophy will

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cause diffuse -- can cause diffuse irritation of the vagina, thinning of the vagina. It's not going to cause specific pinpoint pain or palpation of a mesh causing pain.

It can cause some burning with sexual activity. It does not cause, usually, discomfort with normal, daily activities.

So that is always in the differential diagnosis. I ruled it out in this one, again, because the suspicion on exam of palpating the sling.

Q. Are you saying that vaginal atrophy isn't playing any type of role here?

A. It can be a very mild complicating factor. If vaginal atrophy is the source for the problem, estrogen can help repair it. But it's not going to cause pain along a mesh.

Q. But you can't rule it out completely as a mild complicating factor?

A. I can rule it out 99.9

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percent, based upon my experience, my attendance at national/international meetings, giving lectures on the subject, and daily exposure to patients.

Q. Did she have a rectocele at this point? Well, let me rephrase that.

She had a mild rectocele at the time of the implant; had the rectocele progressed?

A. I'd have to go over -- the notes are classic for a general practitioner family practice-type, but they don't give specifics.

The first note with the nurse practitioner, in March of '17, does not tell me anything of specifics of concurrent prolapse.

Follow-up note with the same practitioner, August 13th, 2018, does not state of the posterior -- it does not state of any prolapse, which is an incomplete note and not acceptable with advanced-level-of-care individual.

And the physical exam by Dr.

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Denam, Mary Denam, on -- unfortunately, I don't think I have a date here on this one. Page 15, starting with the bottom paragraph -- for some reason I don't have a date on that, there needs to be a date -- there's no mention of a posterior prolapse.

MR. BUHR: We've been going for a while, Doctor. How about we take a five-minute break and then come back and finish up with the rest?

THE WITNESS: I'm good, if you want to keep going.

MR. BUHR: I'd like a five-minute break, if you don't mind.

THE WITNESS: That's no problem.

VIDEO TECHNICIAN: We're going off record. The time is 3:14.

- - -

(Whereupon, a brief recess

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was taken.)

- - -

VIDEO TECHNICIAN: We're going back on the record. Beginning of Media File 2. The time is 3:24.

BY MR. BUHR:

Q. I'd like to attach some of the records from The Oregon Clinic as Exhibit-11, I believe. These are the Bates numbers that end in 7 -- well, sorry, from 11 to 22.

- - -

(Whereupon, Exhibit Elliott-11, The Oregon Clinic Records, was marked for identification.)

- - -

THE WITNESS: Okay, I have it.

BY MR. BUHR:

Q. If you go to Bates number that ends in 17, it should be an office visit with Lindsey Waugh, if I'm

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pronouncing that correctly, dated August 23rd, 2018.
A. Okay. I'm there.
Q. And this is one of the reports that you reference in -- or one of the records you reference in your report on Page 15; is that right?
A. That is correct.
Q. And it states at this point that she's having a constant, dull pain with intercourse?
A. Well, constant, dull pain, especially with intercourse.
Q. And it notes that the pain level is 2 on a scale of 1 to 10.
Would you agree with me that that's not severe pain that you describe in your report?
A. Well, on a scale of 1 to 10, it doesn't rank up as severe. It's worse than a 1, but it is not in the highest scores, obviously.
Q. And then in the third paragraph on that page, it says, The

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sling is working great, no leaking.
So her stress urinary incontinence has still been corrected by the Align product, right?
A. That is correct.
Q. Do you see the note that says, Does not use estrogen cream on a regular basis?
A. Correct.
Q. And this is despite being prescribed estrogen cream the prior year by Nurse Practitioner Cool, right?
A. That is correct.
The vaginal estrogen would be for the health of the vaginal tissue, for lubrication during sexual activity. And so it states, And does not have issues with vaginal lubrication.
So the only reason to give her -- or for her to take it would be for a mesh complication. And she's not having exposure, so there's really no reason to be on it.
But that's what it states,

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she does not use it despite what was given to her.
Q. And if you can turn to the notes of physical exam on Bates number 21.
A. Okay. I'm there.
Q. So the external genitalia, it notes, Postmenopausal with moderate atrophy; is that right?
A. Correct.
Q. And then, actually, inside the vagina is postmenopausal atrophic appearance; is that right?
A. That's what it states.
Q. And the estrogen cream would be helpful for that type of atrophy, would you agree with that?
A. If she's making the right call that it's due to atrophy, that would theoretically help, if she can tolerate it.
Q. And then it notes, The posterior compartment prolapse to level of the hymenal ring.

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A. Correct.
Q. What stage prolapse is that?
A. Stage 2.
Q. It's a stage 2 rectocele she has now, right?
A. Correct. It's to the level of the hymenal ring. It doesn't say it goes beyond. That would be a stage 2.
Q. And under impression it notes that she has symptomatic posterior compartment prolapse.
What symptoms was she having related to that prolapse?
A. Well, from the note, she denies feeling a vaginal bulge. She does feel some pressure towards her rectum.
So that would be the posterior prolapse symptoms.
Q. Can posterior prolapse cause pelvic pain and dyspareunia?
A. It can cause a sense of fullness and pressure, but it would not cause a tender-to-palpation issue like she had on her exam.

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Q. And that rectocele hasn't been repaired at any time subsequent to this; is that right?
A. I have not reviewed any records stating that it has been repaired, correct.
Q. So she would still be expected to have symptoms related to that posterior prolapse, right?
A. Prolapse symptoms tend not to go away, so I would expect for her to still have symptoms.
Q. And even though she states that she doesn't believe she has any trouble with lubrication, vaginal atrophy can cause painful sex, right?
A. It can cause irritation and burning with sexual activity, which is usually treated with a lubricant -- or can be successfully treated with lubricant or the vaginal estrogen.
But, again, it won't cause tender-to-palpation or specific pinpoint pain.

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Q. There is no evidence of mesh extrusion at this visit, right?
A. There is no report of mesh exposure.
Q. And then she's referred to Denman.
And I think that's what you were referring to prior to our break?
A. Correct.
Q. And that's when Dr. Denman notes that she has pelvic pain with intercourse and feels a bulge with and after a bowel movement, right?
A. Correct.
Q. And so could some of that be related to her rectocele?
A. That's why you would need the physical exam to confirm it. A physical exam will tell you if she has the rectocele, palpation in certain areas, pelvic floor, et cetera.
Again, that's why the physical exam is so important.
Q. And Dr. Denman even notes

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that she was on vaginal estrogen for a period of time but not long-term --
A. Correct.
Q. -- correct?
A. Yes.
Q. And she has not had any pelvic floor physical therapy?
A. Correct.
Q. Is that something that can help with pelvic pain?
A. It depends what type of pelvic pain it is. In my experience, pelvic floor myalgia which is de novo, you can have some benefit from it.
Secondary to mesh, I have never had a patient get significant reduction of pain with physical therapy.
Q. Would you agree that Dr. Denman felt that physical therapy was an important part of her plan for Ms. Smith?
A. Well, not really, because she recommended going to surgery fairly soon afterwards. So it was not a serious consideration. She gives it as an

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option.
Q. Let's turn to Dr. Denman's report from August 29th, 2018, which is actually part of that last exhibit.
Do you have that record in front of you?
A. Yes, I do. You're talking Exhibit-11?
MS. GRIFFIN: Correct.
MR. BUHR: Yes.
THE WITNESS: And what page -- I'm sorry, Bates number?
MR. BUHR: The Bates number 11. So the first page of that exhibit.
THE WITNESS: I'm there.
BY MR. BUHR:
Q. So about halfway through the paragraph, under plan, it says, Discussed need for PT -- which I assume is physical therapy -- after surgery to help decrease scar tissue formation as well as decrease pain.
A. Correct. That's what she

Page 114

states.
Q. Do you agree that that's -- do you agree that that's part of her plan, then, and she thought that would help?
A. Well, she discusses it after surgery. It won't have any bearing on scar tissue, but it may help decrease the pain. In my experience, it does not.
Q. Will it help --
A. I'm sorry.
Q. Would it help decrease the formation of scar tissue after the surgery?
A. No, absolutely not. It has nothing to do with that. Unless she's talking about vaginal dilators to help prevent scarring of the vagina. But physical therapy alone does not help with that.
Q. So you think she's just wrong on this?
A. I didn't say that. The note is not clear.

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Who knows what she's thinking. If she's talking about vaginal dilators, sometimes they'll use various different vaginal procedures and stretching. If they're talking about that physical therapy, yes. But that falls into the pelvic floor rehab.
So I can't state what she's talking about here. And if she's referring to the vaginal dilators, then, yes, that will help reduce the narrowing and aggressive scarring of the vagina.
Q. And Ms. Smith hasn't done any type of PT after the surgery, right?
A. I'm not aware of her doing any, no.
Q. Then she also states, Discussed need for perioperative vaginal estrogen to improve healing.
Do you have any disagreement with that part of the plan?
A. For mesh exposure, I think it probably plays a role. For mesh scarring, mesh arm contraction, it will

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have no benefit.
Q. She refers to the -- her impression -- well, strike that.
You can have vaginal scarring after any type of vaginal procedure; would you agree with that?
A. In varying degrees, severity, progression, permanence, inability to fix, that can happen with procedures.
But, again, there's going to be variables with each procedure.
Q. Right. But it's something that's well known and expected, correct?
A. Well, no. It depends upon who you're talking to, their level of knowledge, their level of experience. And then, again, in varying degrees.
Not all doctors read the same books, attend the same meetings. There's variable --
Q. You agree that Dr. Kim testified that she was aware of the risk of scarring and scarification?

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A. She was aware of what she knew but not the full extent of it, as we've talked about before.
Q. Well, again, you don't know the full extent of what she knows?
A. I don't. I'm playing odds that she has not reviewed what I've reviewed. And she knows what she knows, and I have no argument against that.
Q. But there's expected to be a certain amount of scarring around any type of pelvic mesh that's implanted; would you agree with that?
A. All meshes have been shown to increase fibrosis and scarring. Not all meshes are the same, so there would be varying degrees of mesh scarring with a specific product.
Q. And how do you define banded as you refer to it in your report? Is that related to scarring?
A. That is a function of scarring and the product design. And that's referring to, usually, the mesh

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arms, as when they're pulled through, they roll and contract and cause banding. They are palpable, you can feel it. There's a very classic feel to it.

Q. Here, Dr. Denman advised against removing the arms, she doesn't feel there's any problems related to the arms.

Would you agree with that?

A. No, I disagree -- I mean, I agree not to remove the arms, that is a risky, dangerous surgery without any clear benefit.

Now, some surgeons around the United States still do that, or are trying to do it. We still don't know if that's the right way to go. I personally do not remove the arms. Again, it's a very, very difficult, morbid procedure with the risk/benefit ratio more on the risk.

So it's not that Dr. Denman didn't think that was the source of the problem, she didn't feel that it would

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cure the problem.

Q. Well, did you read her deposition testimony where she specifically testified that there was no pain at the arms of the mesh?

A. Correct.

Q. And do you have any reason to disagree with that assessment?

A. Based upon the physical exam at that point in time, she touched the right area, I have no reason to doubt it.

Q. So there's no evidence that she has pain related to the arms of the mesh, right?

A. Well, she had -- she was tender to palpation and she had the thick banding on the anterior wall painful to palpation, 2 centimeters in width at max with lateral arms obturator. So that, to me, tells it's -- the arms are a component to this.

Q. But she specifically testified there was no pain at the arms of the mesh?

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A. I'm just going off of what her note is here. And it seems pretty clear here. Again, thick banding anterior wall painful to palpation, approximately 2 centimeters in width at max with lateral arms, question mark, obturator.

And so I don't know -- we'd have to look at her exact testimony, which may be helpful. But this, to me, seems pretty clear.

But, again, if I were her in her situation, I would not go after removing those mesh arms.

Q. Let's look at her deposition testimony. If you can hand him Dr. Denman's transcript from June 13th, 2019.

MS. GRIFFIN: I'm sorry, Eric, that came in spotty. But we will mark Dr. Denman's deposition testimony from June 13th, 2019. And that will be Exhibit-12.

- - -

(Whereupon, Exhibit

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Elliott-12, 6/13/19 Deposition Testimony of Dr. Mary Denman, was marked for identification.)

- - -

THE WITNESS: Okay, I have it.

BY MR. BUHR:

Q. If you'd go to Page 79.

A. You cut out.

Q. If you'd go to Page 79.

A. Oh, 79.

Q. And this is the individual page number. Because on Page -- because there's four pages per page.

A. Sure. I'm there.

Q. So Page 79, Line 5: So going back to the plan on Page 11, it states here that you didn't find any issues with the arms of the mesh; is that right?

Denman responds: Correct.

And then further down, Line 14: And when you say there were no issues, that's because on examination it

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was not tender there, right?
Her answer is: Correct.
She was not reporting pain there, right?
She responds: Correct.
So would you agree, then, that she wasn't having any pain at the site of the arms?
A. That's what she states. I'm just going off -- we have a discrepancy between her that-day exam and then what she testifies, you know, a year or so later.
But that's what she states. There's a discrepancy here.
Q. Right. Her sworn testimony as she's reviewing her records.
A. Correct, that's what she states.
Q. Are you going to disagree with her assessment?
A. No, that's what she states under oath. I have no reason to disagree. I was just going off of the

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physical exam at the time. But, you know, that's what she states later.
Q. Dr. Denman, in her report, there's a reference to that she discussed likely nerve damage from FAVD, which I believe is forceps-assisted vaginal delivery; is that right?
A. Yes. I would assume so. That's not an abbreviation -- I don't do any OB, so I assume that.
Q. Then it goes on, Episiotomy with delivery. Reassurance there's not a mesh factor involved with this issue, speaking of the fecal incontinence.
And you don't have any disagreement with that, do you?
A. No. A vaginal delivery and episiotomy and, I believe, she had four or five, maybe even six children, which were all decent-sized babies, that, logically, is going to cause fecal incontinence. And it is -- in my opinion, the Avaulta and Align are not associated with fecal incontinence.

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Q. Excuse me for a second.
Are there any more conservative options Dr. Denman should consider before removing the mesh?
A. No. Dr. Denman did a nice job.
Your two options, which we still do not know, I don't know, even though I see this every day, is, what do you do with these individuals? Do you operate or let them be? And then if you do operate, how aggressive do you get? It still remains to be defined.
So I think she did a nice job. She felt this -- she felt the mesh, so she felt surgery to get rid of the mesh was a viable option. So I have no criticism. I think she did a nice job.
Q. Ms. Smith wasn't on any pain medications at this point, was she?
A. No, she was not.
Q. And she had not done any physical therapy, correct?
A. I am not aware of her doing

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any physical therapy.
Q. And she was periodically on estrogen but not consistently, correct?
A. Correct. As I stated before, it won't help with mesh-related pain. But you are correct, she took it intermittently.
Q. Can trigger point injections help pelvic pain like this?
A. Due to the mesh, no. Due to pelvic floor myalgia muscle spasms, they may play a role and have shown some success.
Q. Then they proceeded to the explant on November 15th, 2018.
A. Okay.
Q. And she was noted to have moderate scarring; is that right?
A. That is what she states, Moderate scarring of contracted mesh at the level of the trigone/UBJ.
Q. And, again, you're going to have scarring with any type of vaginal mesh procedure, right?

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A. In varying degrees, dependent upon the specific mesh, you will have some.
Q. It notes that she removed, quote, blue mesh; is that right?
Do you see that?
A. Yes. She makes a specific -- midline blue mesh was noted, meaning that in the middle of that, there was some that was blue.
Q. And you would agree with me that that would be the Avaulta mesh?
A. That is correct.
Q. And Dr. Denman noted that the tissue was really thin, the vaginal tissue.
Is that possibly due to not using estrogen cream consistently?
A. It's due to the presence of the mesh causing chronic inflammation and pending erosion -- excuse me, exposure. And there's granulation tissue, meaning poor healing.
Q. Every patient heals

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differently, would you agree with that?
A. Well, no. I mean, there can be certain patient factors that can slow it down or speed it up. There can be variations there.
Q. And what patient factors -- what patient factors are those?
A. Chronic steroid use, perhaps; markedly advanced age, perhaps.
But we're talking with -- the vagina is different than with abdominal procedures. So the vaginal estrogen content would probably be one.
But the presence, also, of a foreign body in there is the main factor.
Q. And vaginal atrophy can be a factor.
But if I understand your testimony right, you believe that vaginal atrophy itself was caused by the mesh in some fashion?
A. Well, I'm saying that's a contributing factor, a major contributing factor.

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If vaginal atrophy, just using logic here, were a major aspect of poor vaginal healing, then all of the hundreds of transvaginal repairs I do without a foreign body would also be breaking down and having exposure, and they're not. I don't get any, zero.
We watch our patients very closely with questionnaires, telephone follow-ups, seeing them back in clinic, wound breakdowns in the vagina.
With meshes, you know, there is the known risk of the granulation tissue -- granulation tissue, poor healing, inflammatory process.
So I'm saying in Ms. Smith, looking at all the factors, the presence of the foreign bodies and the inflammation is causing her thin tissue breaking down and the scarring is causing the pain.
Q. But would you agree with me that not every patient that has transvaginal mesh results in vaginal

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atrophy and thinning of the vaginal wall?
A. You are correct. Not every patient has bad outcomes like Ms. Smith.
Q. Right. So in some fashion, it's a patient factor?
A. Well, no, I disagree with that. I mean, if there's a known risk factor that we can point at in Ms. Smith that the Bard people know about, then it's got to be in the IFU. But there's nothing in there.
They have some contraindications, I believe, it's just for pregnancy, bleeding problems. But that's it. So to blame her is to be blaming, what, 20, 30 percent of the patients who have Avaulta? So I don't think that's right. I don't have any logic to go off of for that.
Q. The fact is that some patients have complications from surgeries and some patients don't?
A. That is a fact, yes.
Q. Right?

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A. Correct.
Q. So, then, after the procedure -- well, first, let me confirm, the Align sling is still performing as intended in correcting the stress urinary incontinence, correct?
A. From everything I know at this point, you are correct.
Q. And I believe her last -- well, let's look at your report.
You reference a visit with Dr. Denman on December 3rd, 2018 on Page 17 of your report.
A. Correct.
Q. And I think that might be an incorrect date.
MR. BUHR: Let's attach as Exhibit-12 the report from Dr. Denman, January 2nd, 2019.
MS. GRIFFIN: Okay. We will be attaching this as Exhibit-13.
- - -
(Whereupon, Exhibit Elliott-13, 1/2/19 Dr. Mary Denman

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Report, was marked for identification.)
- - -
THE WITNESS: Okay, I have it.
BY MR. BUHR:
Q. So not that it's a controversial issue, but just for the accuracy of the report, what you reference here as December 3rd, 2018 appears to be from this January 1st -- I might be corrected.
A. I think it's correct. If we look at Bates Number 32, that's 12 -- it's, what, two pages in? 12/3/18, first post-op exhibit. Then if you go to Page 33, exam, vaginal incision. And then that's less than 5 centimeters separation. So I think that date is correct.
Q. You're right.
In your report, you don't have the January 2nd, 2019 report, right?
A. That is correct, yes.

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Q. Okay. So for the December 3rd, you have a, quote, Small area of midline granulation tissue.
Well, actually, I think the quote is that there was a separation along the incision with good granulation tissue.
Do you see that on Page 33?
A. Yes, I do. I -- yeah, so the December 3rd quote -- well, there's not a quote. It says, Small separation of vaginal incision measuring less than .5 centimeters.
And then I do quote the follow-up visit on January 2nd, that's what you were referring to. But I don't see the physical exam on that one.
Q. Okay. We'll just -- that makes sense. Sticking with Page 33.
Do you know what she means by "good granulation tissue"? What does that mean to you as a doctor?
A. This is a fresh post-op. This is two weeks after surgery. You

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expect to see granulation tissue there.
It just means that it's in the very early healing periods. It's healing appropriately.
Q. And it was nontender to palpation on December 3rd, 2018?
A. That is correct.
Q. And then going to January 2nd, 2019, which is the last report we have -- is that right? This is the last report we have from the doctor?
A. That's the last that I have, yes.
Q. And her vaginal exam is nontender?
A. Correct.
Q. And there's a small area of midline granulation tissue?
A. Correct. That's in my report and on this -- from this date.
Q. And she prescribes estrogen again for her?
A. I don't know if she prescribed it. But it states, Estrace to

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vagina, which would be an estrogen cream.
Q. And that would be to help with the healing?
A. Correct.
Q. And she okays her for intercourse after two weeks.
Do you have any criticism of that, based on what the exam showed?
A. I personally would wait until it's completely, 100 percent, healed up. So I don't go by a date. Six weeks out is usual timeframe. And so she's postponing it another two weeks.
So Dr. Denman's assessment was that it would be safe at that point in time.
Q. But she doesn't examine her and confirm that the healing is complete before authorizing intercourse; is that fair?
A. I do not see that in the records anywhere.
Q. And if Ms. Smith had vaginal intercourse before the -- her vaginal

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wall had completely healed, could that contribute to continued problems healing?
MS. SCARCELLO: Objection.
You can answer.
THE WITNESS: Well, I would need to know -- I mean, we're talking in theory here.
With this small area of midline granulation tissue, I don't know how extensive that is. I feel that Dr. Denman, in her experience, must have felt it was mild. And then two weeks would have been safe.
If she went -- preceded those two weeks, or within that two weeks had intercourse, that might not be the ideal. If she waited until afterwards, Dr. Denman felt it was safe.
BY MR. BUHR:
Q. Thank you. But I think my question was, if you have sexual intercourse before the vaginal wall is

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completely healed, can that contribute to continued healing problems?
MS. SCARCELLO: Same objection.
THE WITNESS: I would agree with you. It's definitely not going to help.
BY MR. BUHR:
Q. And you, in your report, are offering certain opinions about Ms. Smith's likely prognosis; is that right?
A. That is correct.
Q. And you describe her prognosis as poor?
A. That is correct.
Q. And you wrote this report before reading Dr. Denman's testimony; is that right?
A. That is -- yes, that is correct.
Q. And Dr. Denman testified that her pain and dyspareunia is markedly improved since the 2018 surgery; is that right?

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A. That is correct.
And that is also my experience on early post-ops after meshes. You usually have a period that the pain is less and it comes back, in my experience, and in the experience of individuals who have written papers on this subject.
I hope it doesn't, but it usually comes back.
Q. So are you saying -- are you offering an opinion, to a reasonable degree of medical certainty, that her pain is going to return?
A. Based upon my experience, my attendance at national/international meetings and my giving lectures on the subject, my dealing with patients, and I've operated on these types of patients, that the odds are greatly that pain will come back.
Q. So can you state, with a reasonable degree of medical certainty, that the pain will come back?

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A. Just as I already stated, with all those aforementioned criteria, that pain usually does come back.

And that's why I have chosen to stop operating for these conditions for pain. And that's also based upon a paper by Ho, et al., H-O, et al., where the poor success of operating for pain, because it doesn't work.

Q. But you would at least agree that at this point it's markedly improved?

A. Correct. And that is wonderful. And I hope I'm wrong. And if I'm wrong, that's wonderful for Ms. Smith.

I just -- in my experience, it doesn't last.

Q. So it may come back but it may not; is that fair?

A. The odds are, based, again, the Ho, et al. -- I believe it's Ho, it's a Zimmerman -- Phillipe, Zimmerman, at UT Southwestern, talks about roughly a 70

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percent chance that the pain comes back or is not cured by surgery.

Again, if I'm wrong, that would be wonderful for her. But, unfortunately, experience has told me otherwise. I've had many patients. I do surgery on it, and they have great pain relief, and we're thrilled, and then disappointed months later or years later.

Q. In Dr. Denman's testimony, she describes some more -- a more recent visit with Dr. -- I'm sorry, let me start over.

In Dr. Denman's testimony, she discusses a more recent visit with Ms. Smith where she had some lateral muscle pain.

Are you offering any opinion about the cause of that lateral muscle pain?

A. I would have to see that actual report before I could state definitively. Lateral is very worrisome for the arm pain, mesh contraction.

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Q. Did you see Denman's testimony that she could not conclude the cause of it?

A. Yeah, we would have to look at the specific report. I recall her stating that.

Q. And she didn't note any muscle pain prior to the explant in the same area; is that right?

A. Again, we need to look at the specifics. I would be going off of memory, so it wouldn't be fair. I have the report here.

Q. Well, we don't have the report from --

A. I'm sorry, deposition. I'm sorry, you said deposition, I thought.

Q. I think it's on Page 55.

A. Okay. I'm there.

Q. So she was having a little increased pain?

A. Correct. That's what I'm -- that's what I'm describing. In my experience, that fits perfectly.

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You have an initial good response, and then it comes back. Again, I wish I were wrong, but that's what happens.

Q. But do you see how she describes this as muscle pain on Line 9?

A. Correct.

Q. And then says she does not -- she does not know what's causing that muscle pain?

A. Yeah. I agree she doesn't know what's causing it.

Q. So I'm saying, to a reasonable degree of medical certainty, she doesn't know what's causing it, can you state -- you can't state, to a reasonable degree of medical certainty, what's causing it without examining the patient, correct?

A. An exam would be very beneficial. I can state, based upon my experience of doing probably hundreds of these, that she has pain that's coming back. It's in the muscles due to the

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presence of the arms; going through the various different muscles from the obturator foramen bilaterally.

Dr. Denman, no criticism to her at all, doesn't know because she just hasn't done these. This is probably her one and only time she's done this. So I don't criticize her. She doesn't know, she admits it, which is very admirable.

And I'm saying, with a reasonable degree of medical certainty, it's due to the presence of the mesh arms.

Q. If you'd turn to Page 35 of her deposition.

A. Okay, I'm there.

Q. The very last -- Lines 24 and 25, where it says she didn't have any muscle pain, so this was prior to the explant, she didn't have pain in the same area where she's complaining of pain now.

So wouldn't that make it less likely to be related to the mesh?

A. It's a progression of the

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fibrosis and scarring. They know from animal models, from, like, Closter, Hoffin and others, that the mesh extraction continues indefinitely. They have dog studies 15 years, 20 years out. So this is the natural progression of it.

Q. After the mesh -- the central part of the mesh connecting the arms has been removed?

A. Yes. But the mesh arms are still going through the obturator foramen connected to -- off the top of my head I would say it's six or seven different muscles. So the mesh continues to contract, and you get continued pain.

Q. Does Ms. Smith have back pain, lower back pain?

A. Yes, she does.

Q. Can that radiate into the pelvis area?

A. Not causing specific pinpoint pain. That's where an exam would help sort that out.

But back pain is in the

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back. You can have radiculopathies going down the legs. Again, it just depends upon where this pelvic pain is.

If it's mid vault, is it obturator foramen versus if it's in the low back -- if it's in the low back, I agree with you, it's not due to the mesh.

Q. And we just don't have the detailed descriptions, as we sit here today, to completely rule out pain radiating from her back?

A. Well, I have no medical records describing her back pain and where that pain is and where it radiates to. If we had that, that would help sort out the issue.

I'm saying that when you put all the factors together of having a large volume of mesh put through the obturator foramen, having mesh contraction and pain, removing it, and in my experience, in the literature, 50 to 70 -- 30 to 50 percent mesh arm contraction rate, everything fits as far

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as it being with mesh.

But definitively answering the question would require either an IME or an advanced expert to examine her and telling us otherwise.

Q. But you would agree that the pain is still markedly improved over prior to the explant?

A. I can't say that. She says it's increased. But it's -- there's no indication that it's back to where it was. I forget, we were on Page 35, I believe.

Q. 55.

A. 55.

Q. She describes it as having a little increase in pain.

A. Yeah. So that would imply, to answer your question, yes. As of that -- the last exam, which I don't have the records from that, she states she was having a little increase in pain. You're correct.

Q. Do you have any opinion on

Page 146

what future care Ms. Smith may need?
A. In my opinion, the only chance for some improvement would be very aggressive advanced-level physical therapy, biofeedback, bladder retraining; questionable injections into the mesh, around the mesh. In my experience, that has worked very poorly.
The other option is surgery to remove the mesh arms. In my experience, that tends not to work very well and can make the pain worse. There are surgeons around the nation who do go after that. I have just felt the risk outweighs the benefit.
So she has options, none of them are really good options.
Q. That would depend on whether her pain returns and, if so, how much --
A. Correct.
Q. -- right?
A. Correct.
Q. So as of today, you're not offering an opinion that she's going to

Page 147

require any further surgeries; is that fair?
A. I'm saying that I would have to wait and watch with time. If she only now, or whenever this last exam was, has a little increase in pain, then she should not undergo surgery.
Q. Do you have any opinion as to whether she will require future surgery to repair her rectocele?
A. Well, a rough estimate is that roughly a third of women have their prolapse progress to needing surgery. So that's just a rough idea.
But it would be immaterial to the Avaulta. It's a separate problem.
Q. Right. But further surgeries related to -- for an unrelated rectocele could result in more pelvic pain and dyspareunia, correct?
A. Well, we're talking, in theory, she could. But she wouldn't have any mesh-related pain. Again, we're talking in theory.

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Right now she doesn't warrant it. So I don't have specifics where I can give an answer to that one.
Q. But, in general, in terms of the known risks of repair of pelvic organ prolapse, it can result in pelvic pain and dyspareunia, right? Even without mesh?
A. You have to put qualifiers on there. There's varying degrees, severity, progression, inability to fix it. But the posterior prolapse can be associated with it. But, again, it's not to the severity that we see with the meshes.
Q. And if she would have had -- one of -- well, let me start over.
One of the safer alternatives that you allege in your report is repair with biologics. And that's both for stress urinary incontinence and pelvic organ prolapse.
But those types of repairs also include the risk of pelvic pain and

Page 149

dyspareunia, right?
A. Not to the degree that we see with the meshes and the severity and the progressive nature of it. So no.
Q. But there's risks and benefits to both of those procedures, right? And the doctor has to make that risk/benefit analysis?
A. If that physician, he or she knows all of the risks known to the company, the severity, the progressive nature of it, and the inability to repair it with the meshes -- again, there's too many variables to give a blanket statement to.
Q. Let me say it this way: Using a biologic -- which, first of all, a biologic is not a similar product; it's a completely different product, right?
A. It is a non-mesh product, yes.
With her situation, biologics would be way down the list. It would just be use of standard absorbable

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sutures that cost $5, would be what I would do with her.
Q. For the treatment of her pelvic organ prolapse?
A. Correct. With the stage 2 anterior prolapse like she had, a standard suture repair of five or six sutures, or less, that cost all of, again, $5, would be what I'd do.
I would not go down the route of biologics. They are theoretically an option. But she had a relatively mild prolapse, so I wouldn't do that. It's an option, but it wouldn't be what I would do.
Q. So, again, that's not utilizing any type of transvaginal mesh, then?
A. Correct.
Q. What about for treatment of stress urinary incontinence?
A. Then you can use her own tissue. You can use tissue from a tissue bank. Then you could use biologics.

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Others are available. Using her own tissue is the easiest and cheapest.
Q. And the use of biologics wouldn't completely eliminate her risk of pelvic pain and dyspareunia, correct?
A. As we mentioned before, I go based upon my previous testimony, depending on the severity, the frequency, the progressive nature of it and the inability to repair it is going to be different with the biologics.
You don't see those problems with it. You see recurrence, but you don't see those other chronic, lifelong problems.
Q. But recurrence is a major consideration in determining what procedure is best for the patient, would you agree?
A. It is a consideration. If you asked the patient, would you rather have a recurrence of your prolapse or lifelong pain and inability to have intercourse, those are two different

Page 152

things.
Q. The main reason the community, medical community, was looking towards polypropylene mesh was to increase -- or, rather, decrease the risk of recurrence, correct?
A. That was the goal, which is an admirable goal. However, it didn't pan out that way. And so the anatomic repair rate was possibly better in the anterior vaginal vault. But apical and posterior, there was no benefit. So the reoperation rate was the same.
So you increase the complications for the woman without giving her a significant benefit.
Q. Plaintiff's implant procedure was in January 2008, right?
A. Correct.
Q. The only safer alternative that you list that's specific to vaginal mesh is a lighter-weight, larger-pore polypropylene mesh, right?
A. Correct.

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Q. And are you aware of a midurethral sling, at that time, that meets the description in your report?
A. Well, I talked about POP repair. I didn't mention anything as far as a sling.
So that Point Number 3 on Page 19 is a POP repair using a lighter-weight, large-pore mesh. So that's not pertinent to the sling.
Q. What about Number 4 on Page 20?
A. Correct. I am not aware of there being an on-the-market, available, a lightweight, large-pore mesh sling. There were trials of them, but they were never released.
Q. But you believe there was a POP, pelvic organ prolapse, mesh that's lighter weight and larger pore --
A. Ethicon had --
Q. -- in 2008?
A. I'm sorry, I interrupted you.

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I cannot specifically state to 2008. Ethicon did have a product that was out there, but didn't have the arms. The arms are what causes a significant component of the problem with pain.

That's what I'm saying, is that this particular patient, Ms. Smith, did not need those advanced-level repairs. It was a first-time surgery with a low-grade prolapse.

Q. And even if there was a lighter-weight, larger-pore mesh available at the time, it wouldn't have eliminated her risk for pelvic pain or dyspareunia or extrusion, correct?

A. Let's break that down. That's a -- what I call a compound question. I don't know what you guys call it.

We have to define the type of mesh we're doing. If all you're doing is a mesh without the arms -- see, the arms are a major source of the problem -- so your risk of extrusion would

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theoretically be the same, as long as it doesn't have the, you know, like the Avaulta Plus has that confounding factor of the extra layer of tissue on it.

And then you said pelvic pain. Pelvic pain may be less because you don't have the arms.

And I think you said a third thing there, I forget what that was. You had three.

Q. Dyspareunia.

A. Dyspareunia. Dyspareunia has a chance of being less when you don't have the arms, because you don't have the mesh contraction and the pulling that you get with those things.

So that would -- I know surgeons who still will put in those grafts without the arms. I personally don't. I don't think there's a need for it.

And, again, in Ms. Smith's situation, she didn't need it. She just needs standard sutures.

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Q. But to answer my question, it wouldn't have eliminated her risk of pelvic pain or dyspareunia or extrusion?

A. Correct. It would lower it, but not eliminate it.

Q. I don't want to retread grounds from your generic deposition, but you're not aware of any more recent literature finding that the Bard mesh, the Avaulta, has a higher risk of any complications as compared to any other transvaginal mesh; is that fair?

A. As I'm sitting here right now, I cannot recall off the top of my head a document such as that. But I would have to look through the literature for it. And since it's been pulled off the market, no one is researching it.

Q. So it's possible, if she had a different pelvic organ prolapse mesh, that she would have had dyspareunia and pelvic pain and extrusion, correct?

MS. SCARCELLO: Object to form.

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THE WITNESS: Well, it depends what we're talking about.

Are we talking about, like, the Prolift? anterior? Are we talking about the Monarc product? Excuse me, not Monarc, American Medical Systems, the Apogee and the Perigee? There's a lot out there. All of them have their known risks to it.

Again, with -- Avaulta is a unique one with having that outer coating to it, which throws in another variable in a situation.

But the risk with all meshes is there in varying degrees.

BY MR. BUHR:

Q. Looking back at the opinions in your report, on Page 18, we talked earlier about Dr. Kim's testimony that she was aware of the risks of erosion, extrusion, pelvic pain, dyspareunia.

You recall that discussion, right?

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A. Yes, I do.
Q. In your report here, you specifically refer to foreign body reaction and chronic inflammatory response related to the Bard products.
A. Correct.
Q. Would you agree that Dr. Kim specifically testified that she was aware of those risks?
A. As I've already stated, she was aware of what she knows, but does not know the full extent of it.
Q. You also reference painful contracture and banding of the mesh.
Would you agree that Dr. Kim testified that she was aware of those risks as well?
A. As I stated previously, and I'll rely on the previous testimony, she stated what she knew, and she doesn't know the full extent, as I do and others involved in this, what's going on behind the scenes with the company.
Q. So I understand that that's

Page 159

your testimony, that she didn't know the full extent.
But there's no risks that she wasn't aware of that are relevant for Ms. Smith?
A. She knew about risks. But she didn't know about the severity, the frequency and the progressive nature of those risks.
Q. But she was aware of each of the risks and complications that you're opining Ms. Smith had as a result of the Bard products, right?
A. Well, as I've stated, she knew of risks. But she didn't know of the severity, the frequency, the progressive nature and the inability to fix those complications.
Q. Her anterior prolapse that was corrected by the Avaulta, that has still not returned, correct?
A. Based upon the January 2nd, 2019, so, what, six, seven months ago, there was no record of the prolapse

Page 160

coming back.
Q. So both the Align and the Avaulta corrected the conditions for which they were implanted for, right?
A. At a certain cost, you are correct.
MR. BUHR: That may be all the questions I have. If we can just take a quick break and then come back.
THE WITNESS: Sure.
VIDEO TECHNICIAN: We're going off record. The time is 4:25.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: We're going back on record. Media File Number 3. The time is 4:27.
BY MR. BUHR:
Q. So we talked earlier that Ms. Smith had preexisting depression; is

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that right?
A. She was on medication for depression. I don't know how severe it was.
Q. Can there be a psychological component to dyspareunia?
A. Possibly. However, it's not going to cause pinpoint pain and pain at the site of the mesh. That's not -- that's not a component of depression.
And if depression is a major factor in causing complications with meshes, it needs to be on the IFU, which it's not.
So she had a preexisting condition. And that's worrisome if it's not on the IFU, that worsens things.
Q. Well, I wasn't suggesting that it was relevant to the mesh.
But even without mesh, a patient can have dyspareunia due to psychological issues and depression?
A. Well, that's a broad statement. If there's a history of

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physical trauma, rape, abuse of some sort, that's a different story. That becomes very complicated.

But she reported nothing prior to the surgery. This all happened years later. So I don't see a logical connection between the two.

Q. Because she didn't have similar complaints prior to the implant?

A. Well, the location of the pain, the progressive nature of it, the severity all happen years later. So, again, I don't see a logical connection between the depression and this.

Again, if it is a known issue, that's got to be on the IFU.

Q. Can depression and general wellbeing affect the healing process in an individual?

A. As far as it relates to the vagina, I've never heard of anything related to that.

Q. Have we discussed all the opinions you intend to offer in this

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case?

A. All my opinions are included in my report. I don't recall if we've discussed every one.

We've discussed all the opinions you've asked me. Not to be a smart-mouth about it, but I don't know if there's something else here we haven't discussed.

Q. And at this point, you don't have any intention of performing an examination on Ms. Smith? But you might -- you would like to have the opportunity to do that if the case were to go to trial; is that how I understand your testimony?

MS. SCARCELLO: Object to form.

You can answer.

THE WITNESS: Yes. If this case were to go to trial, then I would have to perform an IME prior, to further support or refute my opinions at this point.

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I'll keep an open mind, based upon what's going on.

And the farther she goes out from her revision surgery, it would be important to have a documented exam, too.

MR. BUHR: All right, Doctor, I think that's all the questions I have today.

MS. SCARCELLO: Nothing from me.

VIDEO TECHNICIAN: This concludes today's --

MR. BUHR: Hold on. Before we go off the record.

I just want to make sure we have a placeholder exhibit for the invoices that will be provided by counsel's office.

- - -

(Whereupon, Exhibit Elliott-14, Placeholder, was marked for identification.)

- - -

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MR. BUHR: With that, I think we're done. Thank you.

MS. SCARCELLO: Thank you.

VIDEO TECHNICIAN: This concludes today's deposition. We're going off the record. The time is 4:31.

- - -

(Whereupon, the deposition concluded at 4:31 p.m.)

- - -

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

Amanda Maslynsky-Miller
Certified Realtime Reporter
Dated: August 12, 2019

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 165, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
DANIEL S. ELLIOTT, MD DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____
Notary Public

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